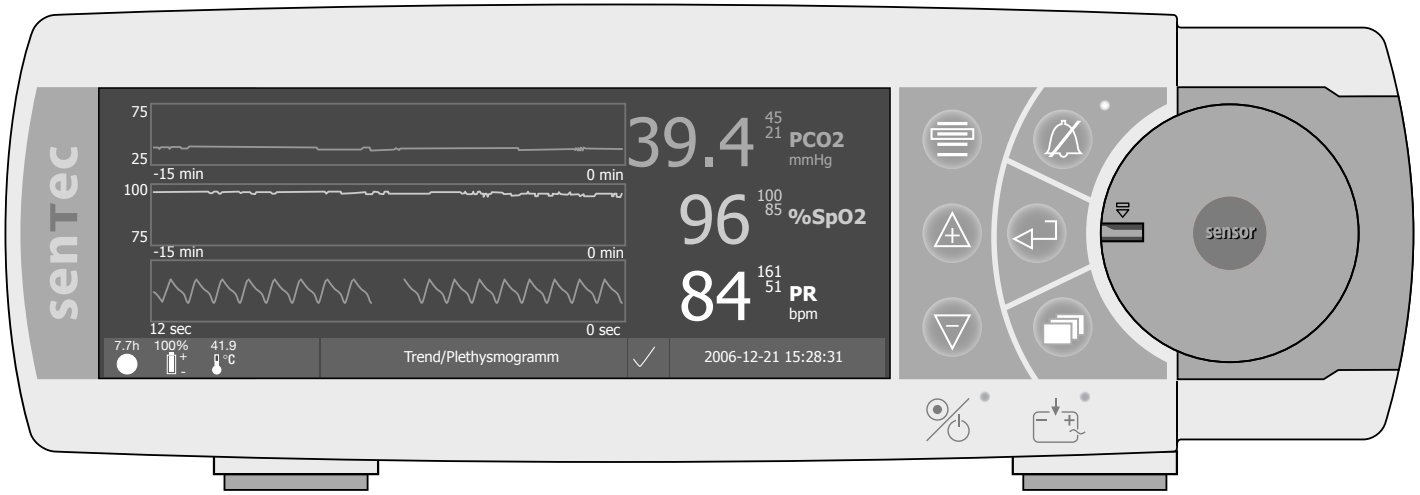
Technical Manual

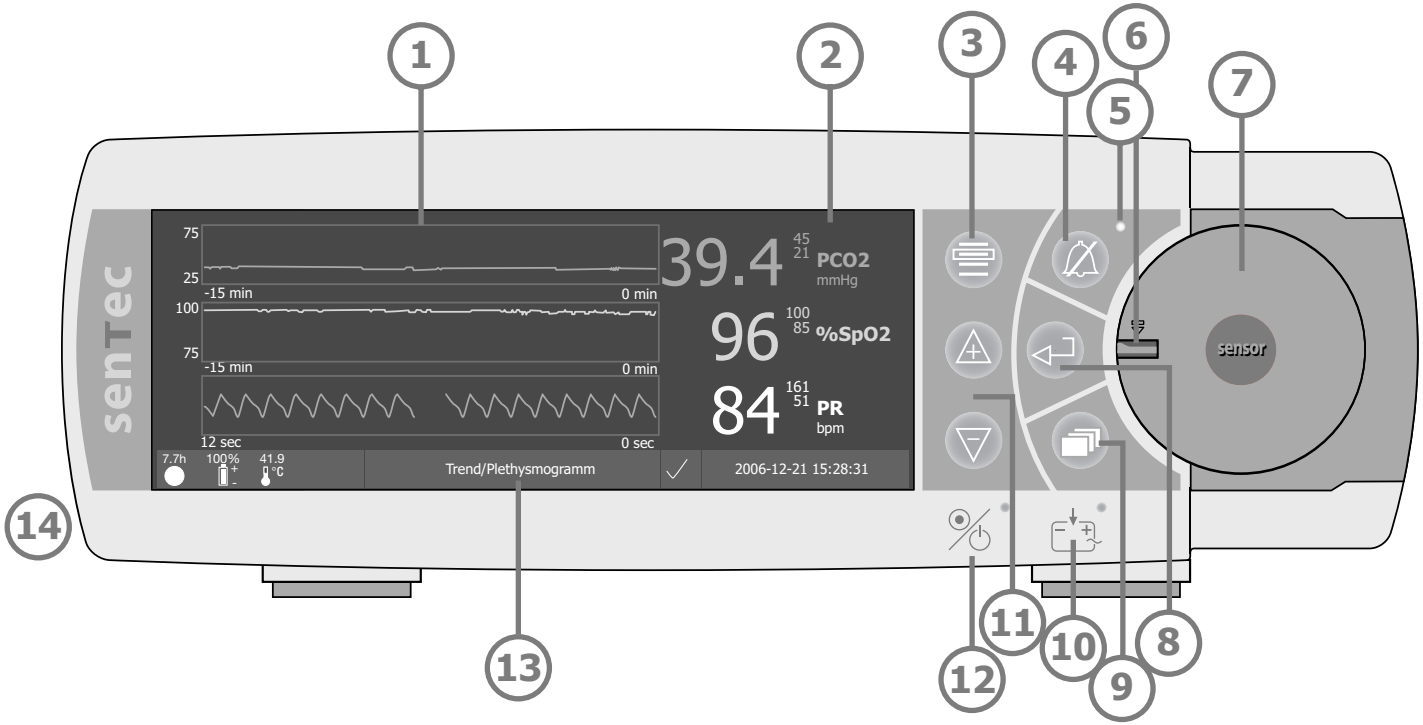
For the sentec Digital Monitor

(Software version SMB SW-V06.20; MPB SW-V04.04)

SenTec Digital Monitor

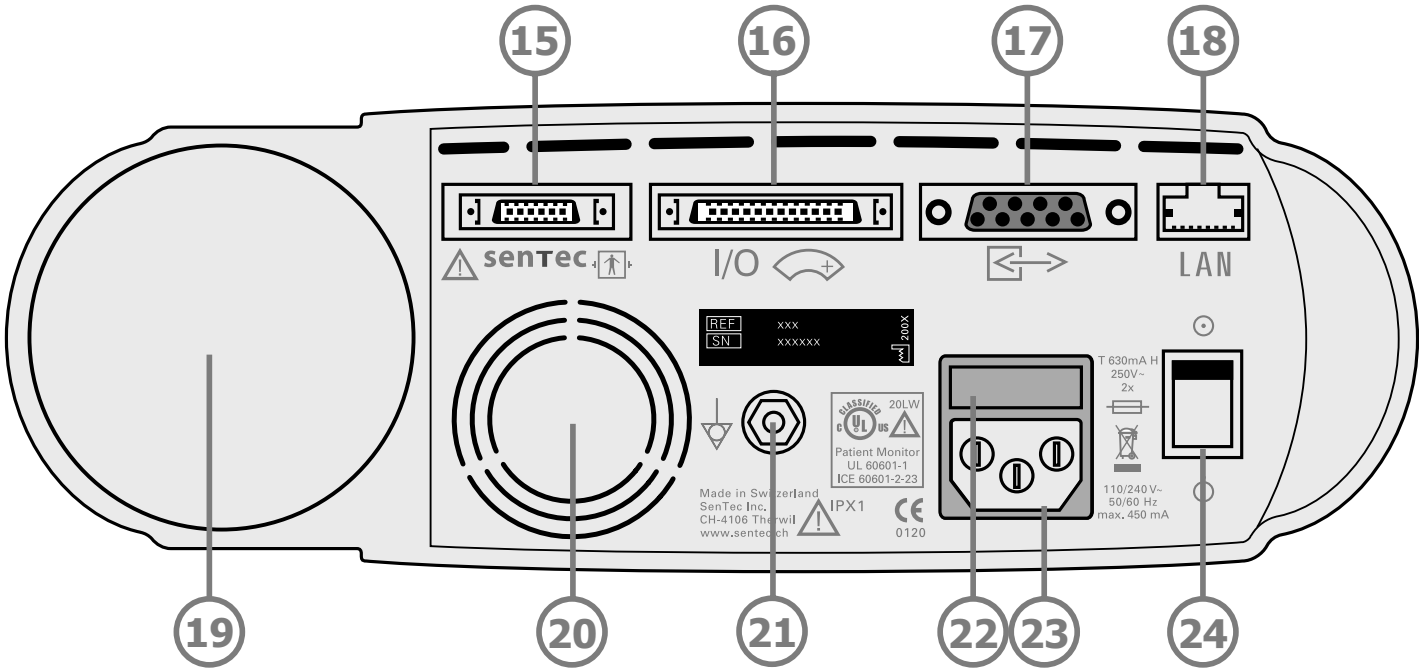
Digital vital-sign monitor





SDM Front Panel

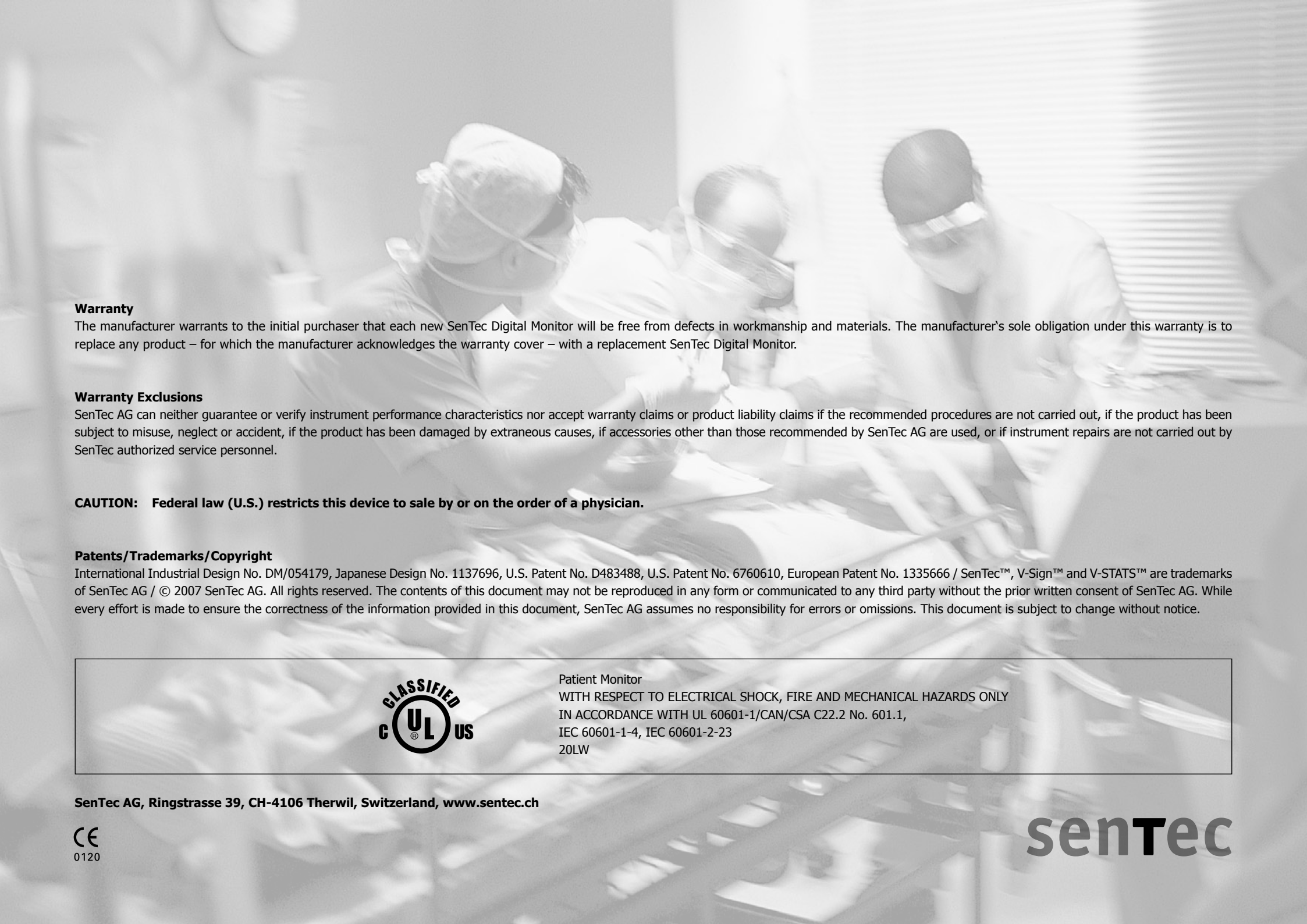
1 Trend Display Area
2 Numerical Display Area
3 Select Button
4 Alarm Mute Button
5 Alarm Mute Indicator (yellow LED)
6 Door Lock
7 Docking Station Door
8 Enter Button
9 Display Button
10 AC Power/Battery Indicator (green/yellow LED)
11 UP/DOWN Buttons
12 ON/OFF Indicator (green LED)
13 Status Bar
14 Speaker (on the side)



SDM Rear Panel

15 Sensor Connection Port
16 Multipurpose I/O-Port (Nurse Call & Analog Output)
17 Serial Data Port (RS-232)
18 Network Port (LAN)*
19 Gas Bottle Slot
20 Fan
21 Equipotential Terminal Connector (ground)
22 Fuse Holder
23 AC Power Connector
24 ON/OFF Switch

*feature not currently available



Warranty
The manufacturer warrants to the initial purchaser that each new SenTec Digital Monitor will be free from defects in workmanship and materials. The manufacturer's sole obligation under this warranty is to replace any product – for which the manufacturer acknowledges the warranty cover – with a replacement SenTec Digital Monitor.

Warranty Exclusions
SenTec AG can neither guarantee or verify instrument performance characteristics nor accept warranty claims or product liability claims if the recommended procedures are not carried out, if the product has been subject to misuse, neglect or accident, if the product has been damaged by extraneous causes, if accessories other than those recommended by SenTec AG are used, or if instrument repairs are not carried out by SenTec authorized service personnel.

CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

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Patient Monitor
WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 No. 601.1,
IEC 60601-1-4, IEC 60601-2-23
20LW

SenTec AG, Ringstrasse 39, CH-4106 Therwil, Switzerland, www.sentec.ch

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Abbreviations

CO_2	Carbon dioxide
DS	Docking Station
LED	Light emitting diode
O_2	Oxygen
$PaCO_2$	Arterial carbon dioxide partial pressure
$PcCO_2$	Cutaneous carbon dioxide partial pressure
PCO_2	Estimate of $PaCO_2$ calculated from the measured $PcCO_2$ (cutaneous blood gas measurement)
POST	Power-On Self-Test
PR	Pulse rate
SaO_2	Arterial oxygen saturation
SDM	SenTec Digital Monitor
SDMS	SenTec Digital Monitoring System
SpO_2	Functional oxygen saturation of arterial hemoglobin as measured with a pulse oximeter

Introduction

The SenTec Digital Monitoring System (SDMS)

The SenTec Digital Monitoring System (SDMS) is designed for the continuous and non-invasive monitoring of carbon dioxide tension (PCO_2), functional oxygen saturation (SpO_2) and pulse rate (PR). The SDMS consists of the following parts:

- SenTec Digital Monitor (SDM)
- V-Sign™ Sensor
- Digital Monitor Extension Cable
- Ear Clip (for sensor application)
- Multi-Site Attachment Rings (for sensor application)
- Sensor Gel (contact liquide)
- V-Sign™ Disposable Set (sensor remembraning tool)
- Service Gas (for sensor calibration)
- V-STATS™ Installation CD (current version)

The V-Sign™ Sensor combines within one digital sensor the technology to measure cutaneous PCO_2 with the optical elements (LED, photodetector) needed for pulse oximetry. The PCO_2 measurement of the V-Sign™ Sensor is based on a Stow-Severinghaus type PCO_2 sensor. The V-Sign™ Sensor slightly raises the temperature at the monitoring site to achieve local arterialisation of the skin, which is required for the cutaneous PCO_2 measurement. Safe temperature operation is achieved using two independent measurement and control systems. The Digital Monitor Extension Cable connects the SDM to the V-Sign™ Sensor.

For SpO_2, PR, and PCO_2 monitoring in adult and pediatric patients the sensor is applied to the patient's ear lobe using SenTec's single-patient use Ear Clip. For PCO_2 only monitoring the sensor is applied to a conventional PCO_2 measurement site using SenTec's single-use Multi-Site Attachment Rings (MAR): model MAR-A/P/N is intended for use for neonates as well as for adult and pediatric patients with fragile and sensitive skin; model MAR-A/P is intended for adult and pediatric patients with normal, intact skin. Upon sensor application a drop of Sensor Gel (or simply a drop of clean tap water) ensures an adequate contact between the patient's skin and the V-Sign™ Sensor: CO_2 diffusing out of the skin is trapped by the resulting liquid layer, rather than diffusing to the surroundings.

The SDM is equipped with an integrated calibration unit, the Docking Station, allowing a fully automatic PCO_2 sensor calibration. The Service Gas containing 8% CO_2 serves as a CO_2 calibration reference. If stored in the Docking Station the V-Sign™ Sensor is periodically recalibrated. This feature ensures that the V-Sign™ Sensor is continuously "Ready for Use". The V-Sign™ Disposable Set provides a straight-forward preparation of the V-Sign™ Sensor: with just a 4 "Press-and-Turn" procedure all necessary steps to change the sensor membrane are performed.

Intended use of the SDMS

- The SenTec Digital Monitoring System - consisting of the SenTec Digital Monitor, the V-Sign™ Sensor and accessories - is indicated for continuous, non-invasive patient monitoring.

- The V-Sign™ Sensor is indicated for use with the SenTec Digital Monitor when continuous non-invasive monitoring of carbon dioxide tension (PCO_2), oxygen saturation (SpO_2), and pulse rate (PR) are required for adult and pediatric patients. In neonatal patients the use of the V-Sign™ Sensor is indicated for carbon dioxide tension monitoring only.

- SenTec's Ear Clip is intended for use with the V-Sign™ Sensor when continuous, non-invasive carbon dioxide tension, oxygen saturation and pulse rate monitoring are required. The Ear Clip is for single-patient use and is indicated to attach the V-Sign™ Sensor to the ear-lobe of the patient. The use of the Ear Clip is contraindicated for patients whose ear-lobes are too small to ensure adequate sensor application.

- SenTec's Multi-Site Attachment Ring, model MAR-A/P/N, is intended for use with the V-Sign™ Sensor when continuous, non-invasive carbon dioxide tension monitoring is required for adult, pediatric and neonatal patients. The Multi-Site Attachment Ring, model MAR-A/P/N, is for single use and is indicated to attach the V-Sign™ Sensor to conventional measurement sites for carbon dioxide tension monitoring.

- SenTec's Multi-Site Attachment Ring, model MAR-A/P, is intended for use with the V-Sign™ Sensor when continuous, non-invasive carbon dioxide tension monitoring is required for adult and pediatric patients. The Multi-Site Attachment Ring, model MAR-A/P, is for single use and is indicated to attach the V-Sign™ Sensor to conventional measurement sites for carbon dioxide tension monitoring.

- The SenTec Digital Monitoring System is indicated for use in hospitals, hospital-type facilities, intra-hospital transport environments, and - if under clinical supervision - home environments.

- The SenTec Digital Monitoring System is for prescription use only.

Note: Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas. Hospital-type facilities typically cover facilities such as surgical centers, special nursing facilities and sleep labs outside of the hospital. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facilities.

Note: The Digital Monitor Extension Cable is indicated for use only with the SDM and the V-Sign™ Sensor. The Service Gas is indicated for use only with the Docking Station integrated in the SenTec Digital Monitor, or with Docking Stations compatible for use with the V-Sign™ Sensor. The Sensor Gel is indicated for use only with the V-Sign™ Sensor. The V-Sign™ Disposable Set is indicated for use only with the V-Sign™ Sensor.

Principles of Operation and Limitations

Cutaneous Blood Gas Measurements: PCO_2

Carbon dioxide (CO_2) can readily diffuse through human body tissue and skin. With an adequate sensor it is therefore possible to measure CO_2 at the skin surface. The V-Sign™ Sensor uses a Stow-Severinghaus type PCO_2 sensor segment to measure cutaneous carbon dioxide partial pressure ($PcCO_2$).

$PcCO_2$ values measured at a specific site and at a given temperature reflect an equilibrium depending on several parameters:

- arterial carbon dioxide partial pressure ($PaCO_2$)
- local skin blood flow
- metabolism (producing CO_2)
- skin structure
- diffusion properties of the skin

For assessing $PaCO_2$, the dependence of $PcCO_2$ from the other parameters is minimized by two measures:

A: Warming up the measurement site:

- increases capillary blood flow in the skin under the sensor (local arterialization) and, hence, diminishes the arterio-venous PCO_2 difference
- stabilizes metabolism
- increases gas diffusion

B: By selecting an appropriate measurement site the influence of the skin structure on $PcCO_2$ is reduced. Suitable sites are skin areas with:

- high density of capillaries,
- ample capillary blood flow,
- thin epidermis and
- little or no deposition of fat.

The earlobe - fulfilling these criteria - is a particularly suitable measurement site, as it can also be used for SpO_2/PR monitoring. Suitable measurement sites for PCO_2-only monitoring include

- for adult/pediatric patients the cheek, the forehead, the thorax under the clavicle, the upper arm, and the skin area behind the ear lobe
- for neonatal patients the thorax, the back, and the thigh

$PcCO_2$ values are usually higher than $PaCO_2$ values. The relative bias between cutaneous and arterial PCO_2 values within the patient population is quite consistent. It is therefore possible to estimate $PaCO_2$ from $PcCO_2$ using an adequate algorithm. Throughout this Technical Manual the abbreviation PCO_2 designates an estimate of $PaCO_2$ calculated from the measured $PcCO_2$. The SenTec Digital Monitor uses an extended version of an algorithm proposed by JW. Severinghaus:

$$PCO_2 = \frac{PcCO_2}{10\text{^}((Tm - 37°C) \times A)} - P_{meta}$$

The Severinghaus approach is to correct $PcCO_2$ as determined at the measurement temperature (Tm) to 37°C using an anaerobic temperature factor (A) and subtracting an estimate of the metabolic increment at 37°C (P_{meta}). The PCO_2 values displayed by the SDM therefore correspond to PCO_2 values that are normalized to 37°C.

Limitations of Cutaneous Blood Gas Measurements

The following clinical situations or factors may limit the correlation between cutaneous and arterial PCO_2 values:

- arterio-venous shunts
- hypoperfused measurement site, e.g. because of low cardiac index, shock, hypothermia, or vasoactive drugs
- condition of patient's skin and subcutaneous tissue
- interference with anesthetic gases

Note: The SDMS is not a blood gas device. Keep the above mentioned limitations in mind when interpreting cutaneous PCO_2 values.

Note: When comparing PCO2 values displayed by the SDM against PCO2 values obtained from arterial blood gas (ABG) analysis, pay attention to the following points:

- Carefully draw and handle blood samples.
- Blood sampling should be performed in steady state conditions.
- The PCO2 value obtained from ABG analysis has to be compared to the SDM's PCO2 at the time of blood sampling.
- The PCO2 values displayed by the SDM are automatically corrected to 37°C (regardless of the patient's core temperature). When performing the ABG analysis make sure to properly enter the patient's core temperature into the blood gas analyzer. Use the blood gas analyzer's "37°C-PCO2" value to compare with the SDM's PCO2 values.
- Verify proper operation of the blood gas analyzer. Periodically compare the blood gas analyzer's barometric pressure against a known calibrated reference barometer.

For additional information on cutaneous blood gas analysis refer to:

- International Federation of Clinical Chemistry (IFCC), Scientific Division, Committee on pH, Blood Gases and Electrolytes: Guidelines for transcutaneous PO_2 and PCO_2 measurement. Ann Biol Clin 1990;48:39-53.
- AARC Clinical Practice Guideline: Transcutaneous Blood Gas Monitoring for Neonatal & Pediatric Patients. Respir Care 1994;39(12):1176-79.
- Severinghaus JW: The current status of transcutaneous blood gas analysis and monitoring. Blood Gas News 1998;7(2):4.

Pulse Oximetry: SpO_2 and PR

The V-Sign™ Sensor uses a pulse oximetry sensor segment to measure functional oxygen saturation (SpO_2) and pulse rate (PR).

Pulse oximetry is based on two principles: firstly oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry) and secondly the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography).

Pulse oximeters pass red and infrared light into a pulsating arteriolar vascular bed and measure changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) serve as light sources and a photodiode serves as photodetector. The ratio of red to infrared light absorbed is used to calculate the functional oxygen saturation (SpO_2).

Pulse oximeters use the pulsatile nature of arterial blood flow to differentiate the oxygen saturation of hemoglobin in arterial blood from the one in venous blood or tissue. During systole, a new pulse of arterial blood enters the vascular bed: blood volume and light absorption increase. During diastole, blood volume and light absorption decrease. By focusing on the pulsatile light signals, effects of nonpulsatile absorbers such as tissue, bone and venous blood are eliminated.

Limitations of Pulse Oximetry

The following clinical situations or factors may limit the correlation between functional oxygen saturation (SpO_2) and arterial oxygen saturation (SaO_2):

- dysfunctional hemoglobins (COHb, MetHb)
- intravascular dyes
- low perfusion at the measurement site
- skin pigmentation
- venous pulsations (e.g. due to use of the earlobe as a measurement site on a patient in steep Trendelenburg position)
- anemia

Note: Oxygen saturation measurement techniques – including pulse oximetry – are not able to detect hyperoxemia.

Note: Due to the S-shape of the oxyhemoglobin dissociation curve (ODC) pulse oximetry cannot reliably detect respiratory problems in patients inspiring supplemental oxygen.

For additional information on limitations of pulse oximetry refer to:

- AARC Clinical Practice Guideline: Pulse Oximetry. Respir Care 1991;36:1406-9.
- Clinical and Laboratory Standards Institute (CLSI). Pulse Oximetry; Approved Guideline. CLSI document HS3-A (ISBN 1-56238-562-3) January 2005.

Safety Information and Components Overview

Safety Information

Warnings

This symbol identifies a **WARNING** statement. Warning statements refer to conditions that may lead to risk or injury for the patient.

WARNING: The SenTec Digital Monitor (SDM) is not intended for diagnosis. It must be used in conjunction with clinical signs and symptoms. The SDM is a transcutaneous blood gas monitor and not a blood gas analyzer.

WARNING: Carefully route and fix cables to reduce the possibility of patient entanglement or strangulation.

WARNING: To ensure patient safety, do not place the SDM in any position that might cause it to fall on the patient.

WARNING: Do not lift the SDM by the sensor cable or the AC power cord because they could disconnect from the SDM, causing the SDM to fall on the patient.

WARNING: Explosion hazard. Do not use the SDM in the presence of flammable anesthetics/gases or in any environment which has increased oxygen content.

WARNING: The SDM is protected against defibrillator discharge. Parameter display may be temporarily affected during defibrillation, but will rapidly recover. Precisely follow the instructions given in the defibrillator manual.

WARNING: During electro-surgery the SDM, sensor and cables are to be physically separated from the electro-surgical equipment. The sensor must not be placed between cutting and counter electrode. The display may be temporarily affected during electro-surgery, but will rapidly recover.

WARNING: The SDM must only be connected to a grounded (3-wire) AC power supply. Ensure that power and protective ground lines are connected correctly.

WARNING: For USA, respectively Japan: Grounding reliability can only be achieved when the SDM is connected to an equivalent receptacle marked HG (Hospital Grade), respectively HGJ (Hospital Grade Japan).

WARNING: To ensure protection of patient, operator and equipment from the effects of defibrillation and diathermy/electro-surgery, cables manufactured by SenTec AG must be used.

WARNING: Patient safety and SDM performance when connected to patients undergoing magnetic resonance diagnostic procedures (e.g. MRI) are unknown. Remove sensors and cables connected to the SDM from the patient during such procedures.

WARNING: Equipment is protected against electrostatic discharge. The display may be temporarily affected, but will rapidly recover.

WARNING: This device has been tested and found to comply with the limits for medical devices according to the IEC/UL 60601-1 (second edition), EN 60601-1-2 and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING: Certain types of mobile telecommunication equipment could potentially interfere with SDM operation. Mobile telecommunication equipment should not be used within five meters of the SDM.

WARNING: Keep the SDM (as well as any discarded parts) out of reach of children under the age of 5 years. Some parts of the SDM are small enough to be swallowed and may block the trachea.

WARNING: Do not spray, pour, or spill any liquid on the SDM, its accessories, connectors, switches, or openings in the chassis.

WARNING: If the SDM has been wetted accidentally it must be wiped dry externally and allowed to dry thoroughly before further use. Let qualified service personnel inspect the SDM.

WARNING: If connecting the SDM to any equipment, verify proper operation before clinical use. Both the SDM and the equipment connected to it must be connected to a grounded outlet. Combinations of equipment must be in compliance with IEC/UL 60601-1 systems requirements. Anyone who configures a medical system by connecting additional equipment to the SDM is responsible for ensuring that the system complies with the requirements of IEC 60601-1-1 and IEC 60601-1-2.

Cautions

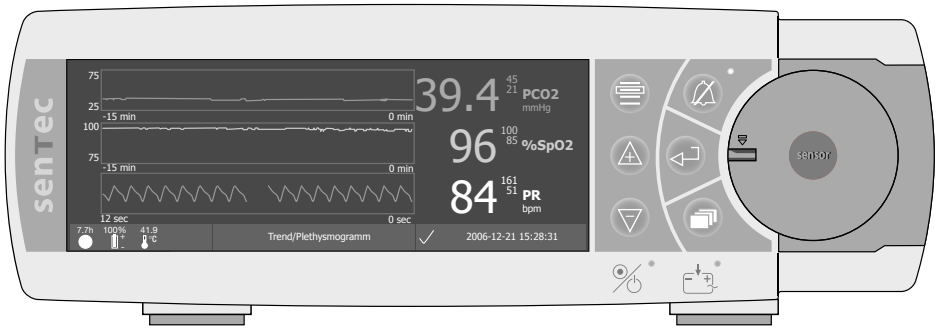
This symbol identifies a **CAUTION** statement. Caution statements refer to conditions that may lead to damage or malfunction of the equipment.

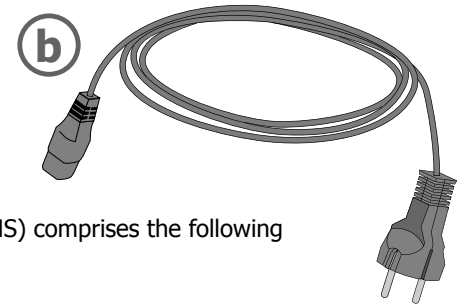
CAUTION: Do not immerse the SDM nor the connectors of any connecting cables in liquid solution.

CAUTION: Do not sterilize any parts of the SDM by irradiation, steam, or ethylene oxide.

Components Overview

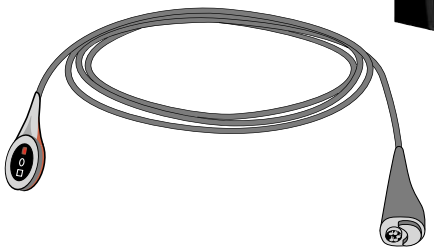
List of components

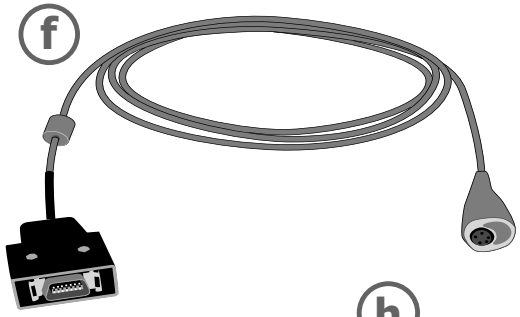


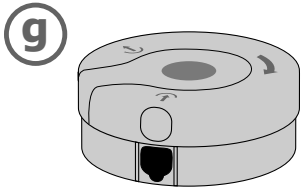


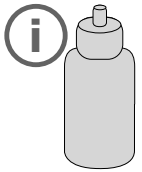
The SenTec Digital Monitoring System (SDMS) comprises the following components:

- ⓐ **SenTec Digital Monitor** (SDM)
- ⓑ **Power cord** (applicable to country of sale)
- ⓒ **SDMS Instruction Manual** (applicable to country of sale)
- ⓓ **SDMS Manual CD**
  (providing detailed information, Technical Manual for the SDM in English only)
- ⓔ **V-Sign™ Sensor**
- ⓕ **Digital Monitor Extension Cable**
- ⓖ **V-Sign™ Disposable Set** (sensor remembraining tool)
- ⓗ **Ear Clip** or **Multi-Site Attachment Ring** (for sensor application)
- ⓘ **Sensor Gel** (contact liquid)
- ⓚ **Service Gas** (for sensor calibration)
- ⓛ **V-STATS™ Installation CD** (current version of SenTec's PC based data download and analysis software)









How to use this manual

All users should read this manual thoroughly. More experienced users of the SDM will be able to go to the appropriate topics to find the information they need.

Related documents

The complete documentation for the SenTec Digital Monitoring System (SDMS) is structured as follows:

- Quick Reference Guide for the SDMS: The Quick Reference Guide summarizes the key essentials on just 2 pages.
- Instruction Manual for the SDMS: The Instruction Manual highlights the essential points when using the SDMS. To ensure proper operation of the SDMS, precisely follow the instructions provided in the Instruction Manual step by step.
- Directions for Use: Additional information on the application of the V-Sign™ Sensor, the V-Sign™ Disposable Set, the Ear Clip and the Multi-Site Attachment Rings is provided in the respective Directions for Use.
- Technical Manual for the SDM: The Technical Manual provides detailed information on the SenTec Digital Monitor (SDM).
- Service Manual for the SDM: The Service Manual provides information on service and repair procedures that do not require to open the cover of the SDM.
- Repair and Service Manual for the SDM: The Repair and Service Manual covers both service and repair procedures on the closed and the open SDM. The Repair and Service Manual will be distributed to SenTec authorized service personnel only.

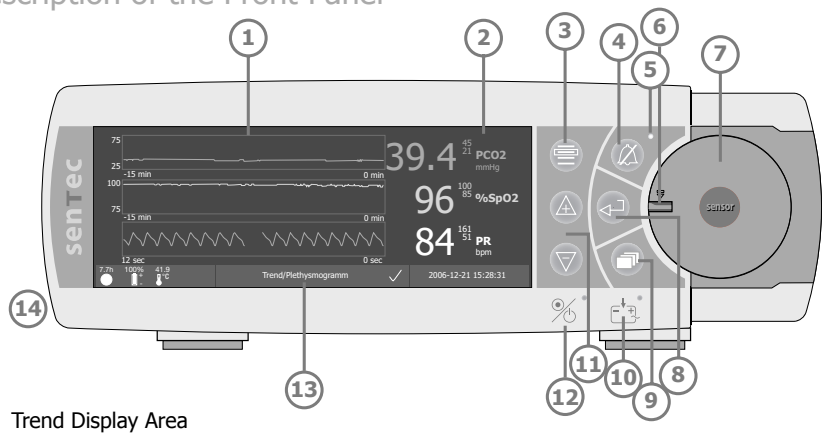
Note: Information/Instructions about the Digital Monitor Extension Cable, Sensor Gel and Service Gas are provided in the Instruction Manual for the SDMS and the Technical Manual for the SDM.

Note: Refer to the Directions for Use of the V-Sign™ Sensor for cleaning and disinfection of the Digital Monitor Extension Cable.

The SenTec Digital Monitor (SDM)

Controls, Indicators and Symbols

Description of the Front Panel



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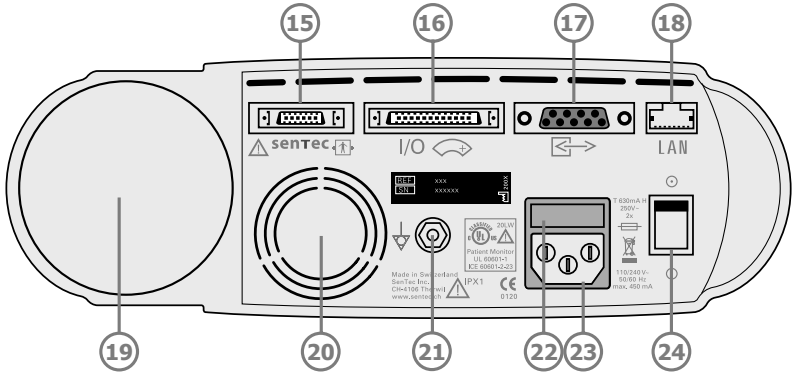
14 Speaker (on the side)

Description of the Rear Panel



15 Sensor Connection Port
16 Multipurpose I/O-Port (Nurse Call & Analog Output)
17 Serial Data Port (RS-232)
18 Network Port (LAN)*
19 Gas Bottle Slot
20 Fan
21 Equipotential Terminal Connector (ground)
22 Fuse Holder
23 AC Power Connector
24 ON/OFF Switch
*feature currently not available

SDM Symbols

The symbols that are located on the rear panel of the SDM are as follows:

Symbol	Name	Meaning
	Attention	See accompanying documents
REF	Reference Number	Followed by the reference number of the equipment
SN	Serial Number	Followed by the serial number of the equipment
	Date of Manufacture	Followed by the date of manufacture of the equipment
	Equipotentiality	Equipotential Terminal (ground)
	ON	Monitor ON
	OFF	Monitor OFF
I/O	Multipurpose Port	Nurse Call + Analog Output
	Nurse Call	Nurse Call (integrated into Multipurpose Port)
	RS-232	Serial Data Port (RS-232)
LAN	LAN	Local Area Network Port*
	Defibrillation Proof Type BF	Degree of protection against electrical shock: Defibrillation-proof, Type BF applied part
	Fuse	Indicates fuse type
IPX1	Type IPX1	Degree of protection against harmful ingress of water: Drip-proof equipment
CE 0120	CE Label	Declaration of conformity of the equipment
c UL us CLASSIFIED	UL Label	Declaration of conformity of the equipment
	WEEE Disposal	European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive: 1. All electrical and electronic waste must be stored, collected, treated, recycled and

	disposed of separately from other waste. 2. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country. **Note:** By recycling materials or other forms of utilizing old devices, you are making an important contribution to protecting our environment.

Table 1: Symbols

* Feature currently not available.

Controls (Buttons)

The following controls are located on the front panel of the SDM:

Button	Name	Function
	Alarm Mute Button	· to mute alarms for 1 or 2 minutes (depending on menu setting) · to mute alarms permanently (if pressing > 3 seconds)
	Select Button	· to access the menu · to scroll through the menu
	UP Button	· to increase the value of the selected menu parameter · to increase brightness of the display (if in Measurement Mode).
	DOWN Button	· to decrease the value of the selected menu parameter · to decrease brightness of the display (if in Measurement Mode)
	Enter Button	· to activate a selected submenu or function
	Display Button	· to switch between the available measurement displays · to return to the measurement display from any menu level

Table 2: Controls (Buttons)

Note: The ON/OFF switch is located on the rear of the SDM (24).

Note: If the audible alarm signals of the SDM are muted, the nurse call function is not active.

Visual Indicators

The following visual LED indicators are located on the front panel of the SDM.

LED	Colour:	Meaning
Alarm Mute Indicator	yellow: blinks yellow: LED off:	Audible alarms muted for 1 or 2 minutes Audible alarms permanently muted Audible alarms active
ON/OFF Indicator	green: LED off:	SDM switched ON SDM switched OFF
AC Power/ Battery Indicator	green: yellow: LED off:	Connected to AC power, battery fully charged Connected to AC power, battery charging Not connected to AC power (i.e. powered by internal battery)

Table 3: Visual Indicators

Additional visual indicators are provided as "Status Icons" and "Status Messages" (see sub-section "Displays").

Audible Indicators

The following table identifies the audible indicators of the SDM.

Function	Description
Alarm Mute Reminder	Signal tone (0.5 seconds) that sounds every 60 seconds if the audible alarms have been permanently muted. Can be disabled by setting the menu parameter "Alarm Mute Reminder" to OFF.
High Priority Alarm	A high-pitched fast pulsing tone indicating a SpO_2, PR, or PCO_2 limit violation (two sequences of five 0.1 second pulses repeated every 10 seconds). Can be muted with the Alarm Mute Button.
Key Click	A short signal tone (0.2 seconds) indicating that a button has been properly pressed. Only active if the menu parameter "Key Click" is set to ON.

Low Priority Alarm	A low-pitched slow-pulsing tone indicating a system status that requires user awerness (one pulse of 1 second repeated every 10 seconds). Can be muted with the Alarm Mute Button. Refer to the section "Status Messages/Status Codes" for a complete list of low priority alarm conditions.
Power-On Self-Test	Acoustic signal to test the loudspeaker during the Power-On Self-Test (three signal tones of 0.2 seconds). Contact SenTec authorized service personnel or your local SenTec representative if this signal is not activated during the POST.
Pulse Beep	Short signal tone (0.2 seconds) that sounds once for each pulse. Its automatic pitch modulation reflects changing SpO_2 levels. Only active if the menu item "Pulse Beep" is set to ON.
Volume Setting	Signal tone (1 second) that indicates the selected volume while changing the volume.

Table 4: Audible Indicators

Displays

Display Configuration

The display of the SDM is configured in 3 areas: the Trend Area, the Numerical Area and the Status Bar. Various preconfigured measurement displays are available, additional displays depend on the system status (Menu Mode, Ready for Use, Sensor Calibration Mode, Sleep Mode, Demo Mode). Whereas the Trend and Numerical Areas change in function of the active display, the structure of the Status Bar remains unchanged.

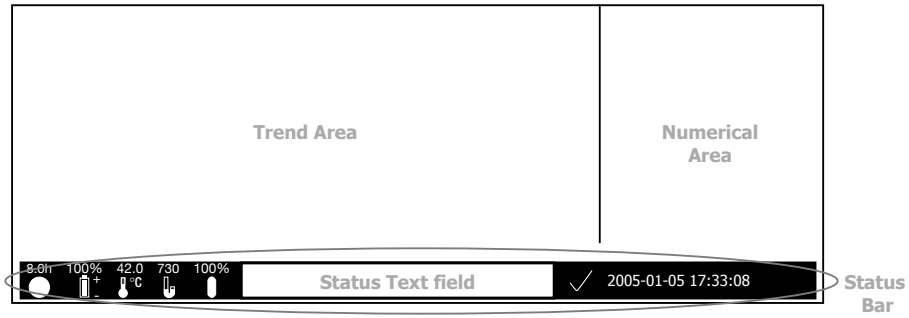


Figure 1: Display Configuration

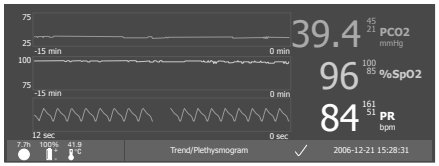
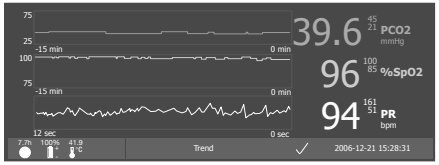
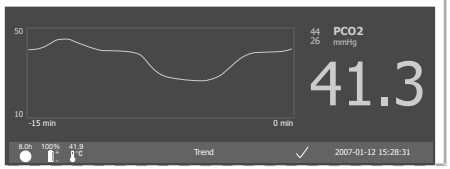
Measurement Displays

Depending on the selected patient type (see "Measurement Settings/Patient") and the enabled parameters (see "Measurement Settings/Enabled Parameters") different sets of preconfigured displays are available:

for "Adult" patients:
· 3 displays for "PCO2 SpO_2 PR"
· 2 displays for "SpO2 PR", i.e. the "SpO_2, PR only" mode
· 1 display for "PCO2", i.e. the "PCO_2 only" mode

for "Neonatal" patients:
· 1 display for "PCO2", i.e. the "PCO_2 only" mode

The display button allows to cycle through and to select one of the available measurement displays. The numerical values of the enabled parameters as well as the corresponding alarm limits are permanently displayed in all measurement displays as well as in the Menu Mode. PCO_2 units are selectable ("mmHg" or "kPa" – see menu parameter "Measurement Settings/Pressure Unit"). The time range of the trends is adjustable from 15 minutes to 48 hours (see menu parameter "Measurement Settings/Time Range for Trends"). The plethysmogram – if displayed - spans a time range of 12 seconds. The displayed trend-ranges for SpO_2, PCO_2 and PR are individually adjustable.

Display Name	Description	Display
Trend/ Plethysmogram	Patient = Adult / Enabled Parameters: "PCO2 SpO2 PR" SpO_2 and PCO_2 are displayed as trends together with the normalized plethysmogram.	
Trend	Patient = Adult / Enabled Parameters: "PCO2 SpO2 PR" SpO_2, PCO_2 and PR are displayed as trends.	
Numerical	Patient = Adult / Enabled Parameters: "PCO2 SpO2 PR" A blip bar - reflecting the normalized pulse amplitude - is displayed together with the measured values.	
Trend (PCO_2 only)	Patient = Adult / Enabled Parameters: "PCO2" PCO_2 is displayed as trend.	

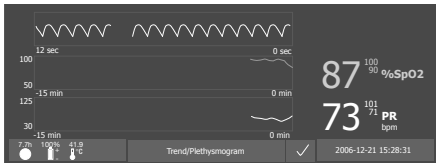
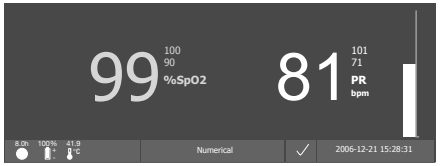
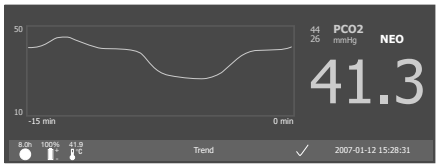
Display Name	Description	Display
Trend/ Plethysmogram (SpO_2, PR only)	Patient = Adult / Enabled Parameters: "SpO2 PR" SpO_2 and PR are displayed as trends together with the normalized plethysmogram.	
Numerical (SpO_2, PR only)	Patient = Adult / Enabled Parameters: "SpO2 PR" A blip bar - reflecting the normalized pulse amplitude - is displayed together with the measured values.	
Neonatal Trend (PCO_2 only)	Patient = Neonatal PCO_2 is displayed as trend. **Note:** If the SDM is operated in the neonatal mode, a yellow "NEO" indicator is displayed.	
	Note: SpO_2 and PR are automatically disabled in the neonatal mode.	

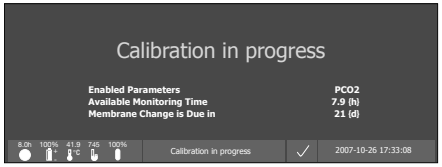
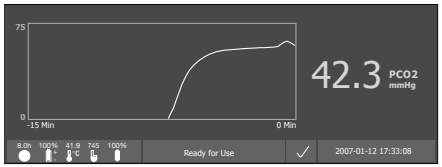
Table 5: Measurement Displays

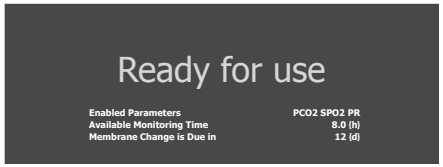
⚠ **Warning:** The measurements of SpO_2 and PR are not defined on sites other than the earlobe. In order to avoid erroneous readings and false alarms of SpO_2 and PR, ensure that the appropriate patient mode (Adult or Neonatal) is selected. For sensor application on sites other than the earlobe in adult/pediatric patients furthermore disable the parameters SpO_2/PR in the menu "Measurement Settings/Enabled Parameters".

Note: A numerical value flashing with a frequency of about 3 Hz indicates an alarm limit violation (high priority alarm).

Note: During the PCO_2 stabilization period, the audible and visual PCO_2 alarm signals are inhibited, the PCO_2 values are displayed in dark grey, the PCO_2 trend curve is not displayed, and the Status Message "PCO2 Stabilizing" is displayed in the Status Bar.

Note: During stabilization periods of the oximetry algorithm, the audible and visual SpO_2 and PR alarm signals are inhibited, the corresponding values are displayed in dark grey, the corresponding trend curves are not displayed, and the Status Message "SpO2 stabilizing" is displayed in the Status Bar.

Display Name	Description	Display
Sensor-Calibration	If the sensor is inserted into the Docking Station the "Sensor Calibration" screen activates. If the parameter PCO_2 is disabled the message "Ready for use" immediately displays.	
	If the parameter PCO_2 is enabled the "Sensor Calibration" screen displays – during sensor calibration - the message "Calibration in progress" which changes to "Ready for use" after successful calibration. The Sensor Calibration screen furthermore displays the status icons and provides important system information ("Enabled Parameters", "Available monitoring time", "Membrane Change is Due in" - please refer to the description of the "Ready for use" screen below for details).	
	If the parameter PCO_2 is enabled it is possible to activate the display of the PCO_2 calibration curve by using "V-STATS" (PC-Software for the SDM). **Note**: The display of the PCO2 calibration curve cannot be disabled/enabled in the menu of the SDM. The selected setting will be maintained at power cycle.	
	If the display of the PCO_2 calibration curve is enabled the status message "Calibration in progress" is displayed in the status bar. A countdown bar indicates the calibration progress.	
	After a successful sensor calibration the status message "Ready for use" is displayed.	
	Note: If the SDM is operated in the neonatal mode, a yellow "NEO" indicator is displayed in the upper right corner of the "Sensor Calibration" screen.	

Display Name	Description	Display
Ready for use	The "Ready for Use" screen informs the user that the SDM and the V-Sign™ Sensor connected to it are ready for use. The "Ready for use" screen immediately displays 15 seconds after the appearance of the message „Ready for use" in the Sensor Calibration screen (see above). **Note:** If the SDM is operated in the neonatal mode, a yellow "NEO" indicator is displayed in the upper right corner of the "Ready for use" screen. The "Ready for Use" screen furthermore provides the following sensor status information: a) "Enabled Parameters": Parameters which are currently activated (use menu parameter "Measurement Settings / Enabeled Parameters" to change the enabeled parameters) b) "Available monitoring time": time interval - after taking the sensor out of the Docking Station or after applying the sensor to the patient – until the SDM will request a sensor calibration or the Site Time will be elapsed, respectively (whichever occurs first). c) "Membrane Change is Due in": days left until next membrane change is mandatory (only displayed if the parameter PCO_2 is enabled). To activate the measurement or calibration screen open the Docking Station door or press any of the control buttons of the SDM, respectively. Low priority alarm situations (e.g. "Gas bottle empty") will also activate the measurement or calibration screen.	
Display Sleep Mode	If the menu parameter "System Settings / Display in Sleep Mode" is set to ON, the display inactivates (display black, back light switched off) in the following situations: a) Sensor On Patient: 30 seconds after the PCO_2 stabilization phase was completed (30 seconds after sensor application if PCO_2 is disabled) b) Sensor in Docking Station: 15 seconds after the "Ready for use" screen was activated The display automatically reactivates when an alarm situation occurs or when the system detects any user action (e.g. opening the Docking Station door, pressing any control button). After disappearance of the alarm situations or if no user action is made the display inactivates again. **Note:** If the SDM is switched off and on again, the display sleep mode setting is retained.	

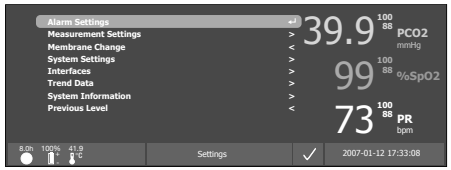
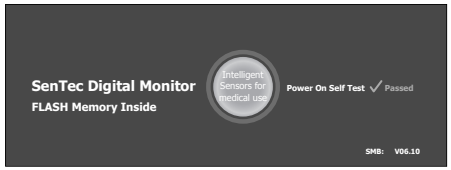
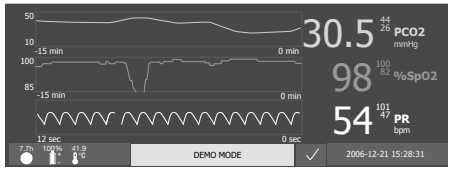
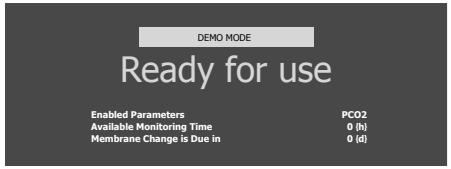
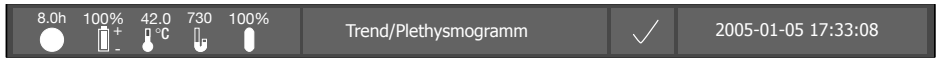
Menu Mode	Example of a menu screen. A grey, underlying bar highlights the selected sub-menu, menu parameter, or function. The symbol on the right of the bar indicates which button is active for this specific menu item.	
POST	Power-On Self-Test (POST) Screen. The result of the POST is indicated on the right-hand side: "passed" or "failed" (if "failed" a corresponding error code is displayed). In the lower right the SMB software version is indicated. **Note:** The message "FLASH Memory Inside" is displayed on the POST screen, if the hardware version of your monitor supports a non-volatile FLASH memory.	
Demo Mode	To activate the "Demo Mode" set the menu parameter "System Settings / Demo Mode" to ON. If the SDM is operated in the "Demo Mode" the status message field is yellow and "DEMO MODE" is displayed in the status message field. **Note:** Simulated patient data are only displayed, if the sensor is neither in the Docking Station nor applied on the patient. If the sensor is a) in the Docking Station the system behaves as usual, i.e. the "Sensor-Calibration" and "Ready for use" screens are displayed. b) applied to the patient, the "Demo Mode" automatically deactivates / can not be activated.	 

Table 6: Additional Displays/Demo Mode

Status Bar



At the left of the Status Bar, five Status Icons provide information on (from left to right) the remaining site time, the battery charge, the sensor temperature, the barometric pressure and the gas level. In the middle, the Status Text Field displays Status Messages. Status messages include display names, information messages and low priority alarm messages. The Status Text Field is followed by the "Status" icon, reflecting the system condition. On the right, the Status Bar indicates date and time.

Status Icons

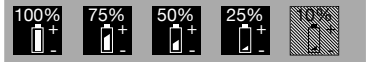
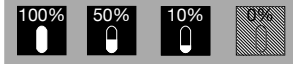
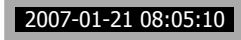
Description	Status Icons
Site Timer: Indicates the remaining site time (hours). A latched low priority alarm is triggered when the preset site time has elapsed. To reset the alarm, you must insert the sensor into the Docking Station.	
Battery: Indicates the remaining battery capacity (%). The icon is highlighted below 10% battery capacity.	
Sensor Temperature: Indicates the measured sensor temperature (°C). The icon highlights if the temperature surveillance of the SDM detects a problem (e.g. over-temperature).	
Barometric Pressure: Indicates the measured local barometric pressure ("mmHg" or "kPa", depending on the menu parameter "Pressure Unit"). This icon displays only if PCO_2 is enabled and if the sensor is in the Docking Station.	
Gas: Indicates how much gas is left in the bottle. This icon displays only if PCO_2 is enabled and if the sensor is in the Docking Station.	
Status: Indicates the alarm status of the monitor. If no alarms are active this icon shows a correct symbol. During alarm situations it changes to an exclamation mark.	
Date and Time: Indicates Date and Time in the following format: yyyy-mm-dd hh:mm:ss.	

Table 7: Description and States of the Status Icons

Note: Check the barometer of the SDM system against a known calibrated barometer monthly.

Status Messages/Status Codes

Status Messages provide technical or physiological information such as display names, system information and low priority alarms. Low priority alarms indicate a system status that requires user awareness.
In the Status Text Field only one message can be displayed at a time. The displayed Status Message therefore corresponds to the message with the highest priority.

Note: The Status Column of the **SenTecLink On-line data output** provides up to 4 Status Codes (in decreasing priority).

The following Table lists all Status Messages in alphabetical order along with the corresponding Status codes (see section "Data Communications").

Message	Code		Description
(no message)	AO	Information	Audible alarms off, i.e. alarms permanently muted.
(no message)	AS	Information	Alarms silenced, i.e. alarms muted for 1 or 2 minutes.
Battery Low	LB	Low Priority Alarm	The remaining battery capacity is below 10% and the SDM is **not** connected to AC power.
Calibrate sensor	CS	Low Priority Alarm	Only if PCO_2 is enabled: Sensor calibration is mandatory. Insert the sensor into the Docking Station. Calibration will start automatically.
Calibration in progress	SC	Information	Only if PCO_2 is enabled: Sensor calibration in progress.
Gas leak in DS	CD	Low Priority Alarm	Only if PCO_2 is enabled: The SDM has detected a Docking Station gas leak. Carefully inspect the door and gasket. If necessary clean with a cotton swab with 70% isopropanol.
Change sensor membrane	RS	Low Priority Alarm	Only if PCO_2 is enabled: Change of the sensor membrane is required. If the change of the sensor membrane is requested the PCO_2 values are displayed in dark grey, the PCO_2 trend curve is not displayed and the audible and visual PCO_2 alarm signals are inhibited.

Connect sensor	CoS	Low Priority Alarm	No sensor connected to the SDM (or sensor / connecting cable defective).
Demo Mode	DM	Information	The SDM is running in the Demo Mode.
Docking Station fault	DF	Low Priority Alarm	Only if PCO_2 is enabled: The SDM detects a Docking Station fault (only indicated if the sensor is in the Docking Station). Sensor calibration will not be initiated or a calibration in progress will be aborted. This alarm resets as soon as the sensor is removed from the Docking Station.
(no message)	DS	Information	This status code indicates that the sensor is in the Docking Station.
Gas bottle empty	GE	Low Priority Alarm	Only if PCO_2 is enabled: Indicates that the gas bottle is empty or no gas bottle is in place. If during an ongoing calibration the gas bottle status changes from "Gas Bottle Almost Empty" to "Gas Bottle Empty" the calibration can still be finished. In the "Gas Bottle Empty" status however, a calibration cannot be initiated.
Insert sensor into DS	ID	Low Priority Alarm	Since more than 2 minutes the sensor is neither stored in the Docking Station nor applied to the patient. This alarm reminds you to ALWAYS store the clean sensor in the Docking Station.
MPB fault	MF	Low Priority Alarm	The MPB surveillance has detected an MPB fault. The MPB is shut down and restarted automatically.
Numerical		Display Name	
PCO2 stabilizing	CE	Information	Only if PCO_2 is enabled: The physiological stabilization time for the PCO_2reading after sensor application is 3-10 minutes. This time frame is needed to achieve local arterialization of the measurement site and to achieve equlibrium between the CO_2 concentrations at the skin surface and within the sensor. During the stabilization time PCO_2 values displayed by the SDM do not reflect arterial PCO_2 values, the audible and visual PCO_2 alarm signals therefore are inhibited, the PCO_2 value is dimmed in dark grey and the PCO_2 trend curve is not displayed.
Ready for use	RU	Information	The SDMS is ready for use.
Sensor fault	SF	Low Priority Alarm	The sensor surveillance has detected a sensor fault (e.g. over-temperature). The sensor is shut down. The SDM has to be switched off and on again.
Sensor off patient	SO	Low Priority Alarm	The sensor has fallen off the patient less than 2 minutes ago.
SpO2 low signal	LS	Information	Only if SpO_2 is enabled: This message is displayed whenever the SDM detects a weak pulsatile signal independently from its severity or the impact on the SpO_2 or PR values. This may be caused by low perfusion at the measurement site.
SpO2 motion artifact	MA	Information	Only if SpO_2 is enabled: This message is displayed whenever the SDM detects the presence of artifacts independent from their severity or the impact on the SpO_2 or PR values.
SpO2 stabilizing	PE	Information	Only if SpO_2 is enabled: During stabilizing periods of the oximetry algorithm, the audible and visual SpO_2 and PR alarm signals are inhibited, the corresponding values are displayed in dark grey, the corresponding trend curves are not displayed.
Site time < 15 min	TL	Information	Indicates that the preset site time expires in less than 15 minutes.
Site time elapsed	TE	Low Priority Alarm	Indicates that the preset site time has expired.
Temp. limiter active	OT	Medium / Low Priority Alarm	The sensor temperature surveillance detected an over-temperature. Electro-surgery or defibrillation may also cause the display of this message.
Trend & Plethysmogram		Display Name	
Trend		Display Name	

Table 8: Status Messages and Status Codes (SenTecLink On-line Data Output)

Power Supply

The SDM can be operated on AC power or on Battery Power for transport and safety during power failure.

Operation on AC Power

The SDM automatically adapts to the applicable local voltage (100 -240V~ (50/60Hz)). If the SDM is connected to AC power, the AC power/battery indicator (10) is lit and provides also information about the charging status of the battery:

- AC power/battery indicator green: battery is fully charged
- AC power/battery indicator yellow: battery is charging

Note: If the AC power/battery indicator is not lit while the SDM is connected to AC power, check the power cord, accessible fuses and the AC power outlet.

Operation on Internal Battery

The SDM has an internal LiIon battery. A new, fully charged battery will provide 6 hours of monitoring time. When the SDM is running on battery the AC power/battery indicator is OFF.

The battery icon in the status bar informs about the remaining battery charge (%). It highlights, the message "Battery low" is displayed in the Status Bar and a low priority alarm begins to sound when the battery level is < 10% and the SDM is not on AC power. If the monitor is not connected to AC power, the monitor will shut off after approximately 20 to 30 minutes (new battery). Plugging the monitor into AC power will mute the audible alarm and the message "Battery Low" dissapears, but the battery icon will stay highlighted as long as the battery level is < 10%.

The monitor cannot operate with a fully discharged battery. Before attempting to turn on a SDM whose battery charge has been completely depleted, first plug the SDM into an AC outlet to allow the battery to charge for a few minutes. The monitor may then be powered on. To charge a low or dead battery, connect the monitor to AC power. Recharging the battery takes approximately 7 hours. 80% of the battery-capacity is available after approximately 5 hours of charging.

Note: It is recommended that SenTec authorized service personnel checks and - if needed - replaces the internal battery every 24 months. Replaced batteries should be disposed of in accordance with local ordinances.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter.

Power-On Self-Test (POST)

After turning on the monitor, the SDM performs a power-on self-test (POST). During the POST the three indicator LED´s on the front panel and the speaker are shortly activated, various components of the SDM are checked and the POST screen is displayed. In the lower right the SMB software version is indicated. If the SDM detects an internal problem during the POST the message "failed" and a corresponding error code (refer to the Service Manual for the SDM) are displayed. If no problems are detected the message "passed" is displayed and after about 30 seconds the SDM switches to the measurement display.

Note: The message "FLASH Memory Inside" is displayed on the POST screen, if the hardware version of your monitor supports a non-volatile FLASH memory.

After the POST check the date/time settings of the SDM and adjust if necessary. The system parameters are set according to the default parameters and the user settings of the parameters in previous sessions. Adjust these parameters if necessary.

Note: To allow configuration of the SDM the menus are accessible during the POST.

Sensor Temperature & Site Timer

Introduction

Warming of the measurement site is important for both cutaneous PCO_2 monitoring as well as for pulse oximetry: as the capillary blood flow in the skin under the sensor increases thus creating a local arterialization, the arterio-venous PCO_2 difference diminishes, metabolism stabilizes and CO_2 diffusion speed increases. Furthermore, warming the measurement site, results in an amplification of the pulse oximetric signal strength.

The ISO 9919:2005 pulse oximeter standard writing committee - being concerned about burns caused by pulse oximeter sensors - recently reviewed published cutaneous blood gas monitoring literature. The committee concluded that it is appropriate to limit the temperature of pulse oximeter probes to 41°C for infants (age < 1 year) and to apply the limits of 42°C for 8 hours and 43°C for 4 hours for older patients (age > 1 year).

To protect against potential burns - resulting from exceeding the allowed application time for a given SET temperature of the V-Sign™ Sensor - the SDM features a Site Timer. The Site Timer allows the counting down from a preset site time. As time expires, the timer triggers a latched low priority alarm. For reliability and patient safety the temperature of the V-Sign™ Sensor is, furthermore, measured and controlled by two independent temperature control circuits. Temperature control and Site Timer are designed to meet the requirements of the IEC 60601-2-23:1999 standard.

Sensor Temperature & Preset Site Time

Based on analysis of the risks and industry practice, the SET temperature of the V-Sign™ Sensor and the preset site time are selected as follows:

Patient group	SET temperature [°C]	Preset site time [hours]
Adults and pediatrics (age > 1 year)	42	8
Neonates and infants (age < 1 year)	41	8

Table 9: Sensor Temperature & Preset Site Time

⚠ **WARNING:** The sensor SET temperature of 42°C shall not be used on patients under one year old.

Note: Higher temperatures and/or longer site times – usually selectable in the case of cutaneous blood gas monitors – cannot be selected in the case of the SDM.

Note: The SET temperature of the V-Sign™ Sensor is fixed to a constant 42°C for adult/pediatrics and to a constant 41°C for neonates/infants. The temperature icon ( ) in the status bar indicates the measured sensor temperature.

Note: Changing the patient mode from "Adult" to "Neonatal" causes a step-change of the SET temperature from 42°C to 41°C. As the current sensor temperature is continuously supervised by the sensor and due to the limited response time of the effective sensor temperature a downward step-change of the SET temperature will intermittently trigger an over-temperature alarm. This alarm will automatically reset as the effective sensor temperature has cooled down to 41°C, i.e. after approximately 10 to 20 seconds.

Note: After changing the sensor temperature a sensor calibration will be requested by the SDM.

Site Timer

The Site Timer of the SDM is a software counter that controls the duration of the sensor application to the patient. Once the SDM detects that the sensor was applied to the patient the Site Timer begins counting down from the preset site time to zero. The site time icon ( ) indicates the remaining site time. The message "Site time < 15 min" displays in the Status Bar once the remaining site time is less than 15 minutes. A low priority alarm sounds, the message "Site time elapsed" is displayed in the Satus Bar and the Site Time icon turns red when the preset site time has elapsed. Remove the sensor from the patient and inspect the measurement site to ensure skin integrity.

Note: Observation of some redness or erythema generally is acceptable as it just implies heat-induced hyperemia and only in rare cases thermal damage to part of the epidermis (first-degree burn). Recovery from skin redness is typically < 1 hour after sensor removal. After observation of any skin irritations, do not apply the V-Sign™ Sensor to the same measurement site.

To reset the Site Timer to the preset site time, insert the V-Sign™ Sensor into the Docking Station ( ).

Note: In order to avoid accidental resetting of the Site Timer, the Site Timer continues the countdown even if the V-Sign™ Sensor falls off the patient. The Site Timer only resets if the V-Sign™ Sensor is inserted into the Docking Station.

Docking Station & Sensor Calibration

Introduction – Why and When to calibrate?

Why is a calibration of the V-Sign™ Sensor needed?

To achieve best PCO_2 results for your patient a properly calibrated sensor is needed. At the end of a calibration, the CO_2 partial pressure of a calibration gas is calculated. If the calibration was successful the calibration value is stored in the memory of the V-Sign™ Sensor and used as a reference for the subsequent patient measurements.

Technical Description – Calibration Chemistry

The PCO_2 part of the V-Sign™ Sensor measures PCO_2 potentiometrically by determining the pH of an electrolyte layer that is separated from the surroundings by a CO_2 permeable membrane. As CO_2 diffuses through the membrane into the electrolyte, it reacts with water forming carbonic acid, which immediately dissociates into HCO_3^- and H^+. The changes in H^+ in the electrolyte layer imply changes in pH and, hence, in the potential measured between a pH glass electrode and a silver chloride reference electrode.

As no charged molecules can penetrate the membrane, the change in pH is strictly due to the carbon dioxide diffusion into the electrolyte. However, at constant CO_2 concentration, any changes in the electrolyte composition (e.g. changing H_2O content, contaminations) will also cause changes in the measured potential and, hence, a drift on the patient's PCO_2 readings. For PCO_2 measurements, it is therefore required to periodically cross-reference, i.e. calibrate, the measured potential with the real CO_2 partial pressure of the surrounding gas mixture.

Note: The course of PCO_2 drift typically causes the PCO_2 readings of the V-Sign™ Sensor to increasingly underestimate the effective CO_2 partial pressure of the surrounding gas mixture.

Minimizing the PCO_2 drift of the V-Sign™ Sensor

The PCO_2 drift of the V-Sign™ Sensor is most prominent (in decreasing order)

- After change of the sensor membrane
- After switching on the sensor/SDM
- After prolonged ambient air exposure of the sensor (> 30 minutes)

To stabilize the PCO_2 part of the sensor and minimize its PCO_2 drift potential, it is recommended to expose the sensor for at least 4 hours to CO_2 gas. The sensor should, therefore, be stored in the Docking Station with the monitor switched on at all times.

Note: If the sensor is neither placed on a patient nor in the Docking Station, a low priority alarm sounds and the message "Insert sensor into DS" displays. After 30 minutes a calibration will become mandatory.

Note: After change of the sensor membrane, prolonged ambient air exposure of > 30 minutes and after switching on the sensor/SDM, we recommend to store the sensor in the Docking Station for at least 4 hours. This time is required for stabilization of the PCO_2 part of the sensor.

When do you need to calibrate the V-Sign™ Sensor?

If a calibration of the V-Sign™ Sensor is needed, the SDM automatically prompts the message "Calibrate Sensor" in the status bar. This is the case in the following situations:

a) Situations requiring an initial calibration
- After switching on the sensor/SDM
- After change of the sensor membrane
- After changing Date/Time by more than 5 minutes
- After changing the patient type from "Adult/Pediatric" to "Neonatal" or vice versa.
- After prolonged ambient air exposure of the sensor (> 30 minutes)
- After the Docking Station surveillance has detected a gas leak

b) After an initial calibration, timer controlled calibrations will be requested
- Within 4 hours after any of the situations mentioned in (A)
- Subsequently every 8 hours

Note: The remaining time until the monitor will request another calibration is indicated in the menu under "System Information/Calibration is Due in [h]".

c) Furthermore, SenTec recommends calibrating the sensor:
- Prior to each monitoring period
- When changing the measurement site

Note: To achieve the highest possible accuracy, the sensor should be calibrated prior to each new patient application. As a minimum - and after the initial 4 hours stabilization period - the sensor must be calibrated once every 8 hours.

Note: If PCO_2 is disabled sensor calibration is not required.

Docking Station

The SDM is equipped with an integrated calibration and storage chamber - referred to as Docking Station - which provides for the automatic calibration of the V-Sign™ Sensor. The Service Gas containing 8% CO_2 serves as the CO_2 calibration reference. The local barometric pressure, measured with a built-in barometer is needed to calculate the expected CO_2 partial pressure applicable during sensor calibration. If the V-Sign™ Sensor is stored in the Docking Station and if the monitor is kept on, the PCO_2 segment of the V-Sign™ Sensor stabilizes because the system automatically calibrates periodically. These features ensure that the V-Sign™ Sensor is continuously "Ready for Use".

⚠ **WARNING:** To maintain monitor readiness always keep the monitor switched on and always store the sensor in the Docking Station.

⚠ **WARNING:** Improper sensor calibration will lead to poor or incorrect PCO_2 readings.

Sensor Calibration

If a calibration of the V-Sign™ Sensor is needed the SDM will prompt the status message "Calibrate sensor". To initiate a calibration, place the sensor into the Docking Station (for directions refer to the Instruction Manual for the SDMS). The Site Timer will reset to the preset site time ( ), the display switches to the Sensor calibration screen, the gas level is displayed in the gas icon ( ), and the barometric pressure is displayed in the respective icon ( ). The SDM furthermore checks the Docking Station and sensor and – if no errors are detected - an automatic calibration starts, i.e. gas containing 8% CO_2 floods the Docking Station chamber.
Depending on sensor performance, the calibration duration varies between 3 and 14 minutes. As soon as the PCO_2 reading stabilizes and achieves the end-point, the sensor is calibrated. Once the calibration is successfully completed, the message, "Ready for Use", appears and the calibration timer resets. The sensor is now ready to be used for patient monitoring.

The PCO_2 value displayed immediately after completion of the sensor calibration (only visible if the display of the PCO_2 calibration curve is enabled) corresponds to the PCO_2 calibration value which is determined by the sensor temperature and the SDM's barometric pressure ( ) reading and, hence, also depends on weather conditions and altitude above sea level.

Note: 15 seconds after a successful sensor calibration, the display of the SDM changes to the Ready for use screen. In the Ready for use mode, the monitor ensures readiness by periodically recalibrating the sensor while stored in the Docking Station. To reactivate the Sensor Calibration screen or the Measurement screen, press any of the control-buttons of the SDM or open the Docking Station door, respectively. Any low priority alarm situation (e.g. "Gas bottle empty") will also re-activate the Sensor Calibration screen.

Note: If the menu parameter "System Settings / Display in Sleep Mode" is set to ON, the Ready for use screen is replaced by a blank Sleep Mode screen. The "Sleep Mode" is characterized as follows: the display is inactive or blackened and the ON/OFF indicator light is lit green. The V-Sign™ Sensor is "Ready for Use", if the SDM is in "Sleep Mode" and if the V-Sign™ Sensor is stored in the Docking Station.

Note: To reset the Site Timer to the preset site ime, place the sensor on the Docking Station door and close the door. A calibration will automatically start, but can be interrupted by opening the Docking Station door. SenTec recommends to complete the calibration.

Note: The "Barometer Icon" and the "Gas Icon" only display if the parameter PCO_2 is enabled and if the sensor is in the Docking Station. Replace the gas bottle if the message "Gas Bottle Empty" ( ) is displayed in the status bar.

Ensuring Calibration Reliability

To ensure continuous reliability of the calibration of the V-Sign™ Sensor, the SDM automatically tests the status of Docking Station and the V-Sign™ Sensor. The following tests are automatically performed:

Automatic Test	Description
Gas flow test	Evaluates the adequacy of the gas flow: If an irregularity in the gas flow is detected a low priority alarm sounds and the message "Docking Station fault" displays. Sensor calibration will not be initiated or, if a sensor calibration is in progress, the calibration will be interrupted.
Calibration gas level	Evaluates how much calibration gas is left in the bottle. If during an ongoing calibration the gas bottle status changes to "Gas bottle empty" the calibration can still be finished. In the "Gas bottle empty" status however, a calibration cannot be initiated.
Docking Station gas leak test	When the sensor is in the Docking Station, the SDM evaluates the integrity of the Docking Station system. If a failure occurs, a low priority alarm sounds and the message "Gas leak in DS" is displayed. If a gas leak is detected, carefully inspect the door and gasket. Clean the Docking Station gasket and sensor with a cotton swab with 70% isopropanol. Remove any residual threads and fibers then reinsert the sensor to calibrate it. Observe the system during 20 minutes to detect any reoccurrence. If the problem persists contact qualified service personnel or your local SenTec representative (troubleshooting list problem P0602).
Sensor performance	If the sensor calibration cannot be completed within 14 minutes after calibration initiation or if the measured electrical potential is out of range, the SDM will request a membrane change. Follow the instructions provided in the Instruction Manual and confirm the membrane change as requested by the monitor. Then calibrate the sensor. If the problem persists contact qualified service personnel or your local SenTec representative (troubleshooting list problem P0304).
Sensor temperature stability	Evaluates the sensor temperature / sensor temperature stability: After switching on the sensor, a sensor calibration is not initiated as long as the sensor SET temperature is not reached. An ongoing calibration is aborted if the sensor temperature is unstable or outside a predefined range.

Table 10: Automatic calibration tests

⚠ **WARNING:** Measurement of the correct barometric pressure is important for a precise calibration. Monthly comparison of the SDM's barometric pressure reading to a calibrated reference barometer is recommended. The comparison should be performed by trained personnel.

⚠ **WARNING:** The correct gas mixture (8% CO_2) is important for a precise calibration. A gas leak in the Docking Station might reduce the effective CO_2 concentration surrounding the sensor during calibration. This gas leak would lead to a faulty calibration resulting in too high PCO_2 readings on the patient. Do not use gas bottles from manufacturers other than SenTec. The use of non-SenTec gas bottles may damage the Docking Station. Different calibration gas mixtures will result in improper sensor calibrations and subsequently result in wrong PCO_2 patient data.

⚠ **WARNING:** The correct gas mixture (8% CO_2) is important for a precise calibration. Make sure, that you handle the interface of the sensor with the Docking Station with care: Always clean the sensor before inserting it into the Docking Station. Do not pull on the cable to open the Docking Station door. Regularly inspect the integrity of the Docking Station door and calibration chamber gasket.

Change of the sensor membrane

Introduction – Why and When to change the sensor membrane?

Why is a change of the membrane of the V-Sign™ Sensor needed?

The PCO_2 measurement of the V-Sign™ Sensor is based on a Stow-Severinghaus type PCO_2 sensor: a thin electrolyte layer is confined to the sensor surface under a hydrophobic, CO_2 permeable membrane. Although this membrane is nearly impermeable to water, the electrolyte dries out over time and therefore needs to be replaced periodically.

When replacing the membrane of the V-Sign™ Sensor with the V-Sign™ Disposable Set, the old membrane is removed, the old electrolyte is wiped off, new electrolyte is applied and a new membrane is affixed (for directions refer to the Instruction Manual for the SDMS).

When do you need to change the membrane of the V-Sign™ Sensor?

Under normal use conditions, the membrane of the V-Sign™ Sensor must be changed

- every 28 days (controlled by a software timer)
- if the performance of the V-Sign™ Sensor is out of range during calibration

In these situations the SDM will request the sensor membrane change to be performed (status message "Change sensor membrane" in the Status Bar/activation of the menu "Membrane Change" upon insertion of the sensor into the Docking Station).

Note: If the preset membrane interval has elapsed the SDM will trigger the message "Change sensor membrane" only upon insertion of the sensor into the Docking Station.

There are additional situations which require to change the sensor membrane, although not explicitly requested by the SDM (no message in the status text field). Perform an "Un-Requested" sensor membrane change in the following situations:

- if the sensor is affected by loose fit of the membrane, trapped air under the membrane or dried-up electrolyte (grey-white appearance of the membrane)
- if the sensor membrane surface is wrinkled, ripped or torn
- after "High Level Cleaning and Disinfection" of the sensor

Note: To perform an unrequested membrane change activate the menu "Membrane Change" and confirm the membrane change with the menu function "Membrane Change Done".

Note: For optimal PCO_2 results following a membrane change, we recommend to store the sensor in the Docking Station for 4 hours, while keeping the monitor switched on. If you do not want to follow the sensor post-membraning instructions and you want to measure immediately, we strongly recommend hourly calibrations for the first 4 hours followed by normal 8-hour calibration intervals.

Note: If PCO_2 is disabled membrane change is not required.

Membrane Timer

The Membrane Timer of the SDM is a software counter, that counts down from the preset membrane interval to zero.

Note: The remaining time until the SDM requests the next membrane change is indicated by means of the message "Membrane Change is Due in [d]" in the menu "Membrane Change", the menu "System Information", on the "Ready for use" screen, and - if the display of the PCO_2 calibration curve is disabled - on the "Sensor Calibration" screen.

Confirming the membrane change on the monitor

The SDM is not able to automatically detect a membrane change of the V-Sign™ Sensor. The user must therefore confirm the membrane change in order to reset the membrane timer to the preset membrane interval.

To confirm a membrane change:

- remove the V-Sign™ Sensor from the Docking Station
- activate the menu "Membrane Change"
- confirm the membrane change with the menu function "Membrane Change Done"
- calibrate the sensor after membrane change

Note: The Membrane Timer resets to the preset membrane interval only if you confirm the membrane change using the menu function "Membrane Change/ Membrane Change Done"

Using the SenTec Digital Monitor (SDM)

Setting Up the SDM

Please refer to the Instruction Manual for the SDMS for setup instructions. The following topics are covered in the Instruction Manual:

- Installation of the Service Gas bottle
- Connecting the Digital Monitor Extension Cable to the SDM
- Connecting the SDM to AC power
- Connecting a sensor
- Turning on the SDM
- Checking the sensor
- Sensor calibration and storage
- Change of the sensor membrane

Additional information on the Power Supply, Sensor Temperature, Site Timer, Docking Station, Sensor Calibration and Membrane Change is provided in the respective sub-sections of this manual.

Language Choice

Choose the language of the SDM user interface in the corresponding menu by proceeding as follows:

Start with any of the measurement displays.

1. Select the menu "System Settings" by pressing the Select Button 4 times.
2. Activate the selection by pressing the Enter Button.
3. Select the menu parameter "Language" by pressing the Select Button three times.
4. Use the UP and DOWN Buttons to choose the language.
5. Select the function "Confirm Language/Main View" by pressing the Select Button once.
6. Activate your language choice by pressing the Enter Button.

Parameter Settings

The SDM is delivered with default parameter settings. Check the settings as described in the annex and change them if needed. At least check the following parameters:

- Alarm limits
- Volume
- Alarm Mute Duration
- Alarm Mute Reminder
- Trendgraph Ranges for SpO_2, PCO_2, PR
- Pulse beep
- Time Range for Trends
- Patient
- Enabled Parameters
- Pressure unit
- Date/Time
- Display settings (brightness, parameter colors)
- Display in Sleep Mode
- Protocol (Serial interface)
- Parameter Range for SpO_2, PCO_2, PR (Analog outputs)

Monitoring with the SDM

Note: For best PCO_2 patient results it is recommended to store the sensor in the Docking Station for the first 4 hours after switching on the monitor, after changing the sensor membrane, or after prolonged exposure of the sensor to air (> 30 minutes).

Instructions on how to attach the V-Sign™ Sensor on the patient and how to detach the sensor after use are provided in the Instruction Manual for the SDMS.

Remember that after sensor application, the PCO_2 reading will typically stabilize after 3 to 10 minutes as the measuring site is warmed up, local arterialization occurs and the CO_2 concentrations in the skin tissue and sensor equilibrate. The PCO_2 values are meaningful only after the stabilization period. Routinely inspect the measurement site to ensure correct positioning of the sensor and skin integrity. Remove the sensor from the patient if the site time has elapsed or if a calibration is required.

⚠ **WARNING:** To maintain monitor readiness always keep the monitor switched on and always store the clean sensor in the Docking Station.

Data Communications

Overview

Patient data acquired by the SenTec Digital Monitor can be output through the multi-purpose I/O-port (analog output; nurse call (16)) or the serial data port (RS-232 (17)), all located on the rear panel of the SDM. These ports can be connected to external instruments such as multiparameter bedside monitors, personal computers (PC), polysomnographs, nurse call systems, chart recorders, or data loggers.

When connecting the SDM to an external instrument, verify proper operation before clinical use. Both the SDM and the external instrument must be connected to a grounded AC outlet. The respective communication protocol setting must be set as described in this section.

Any PC or non-medical instruments connected to the SDM's data ports must be certified according to the IEC 60950 standard. All combinations of equipment must be in compliance with the IEC standard 60601-1-1 systems requirements. Anyone who connects an external instrument to the SDM configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of standard IEC 60601-1-1 and the electromagnetic compatibility standard IEC 60601-1-2.

Multipurpose I/O-port

The multipurpose I/O-port is located on the rear panel of the SDM ((16)). The pin layout of the multipurpose I/O-port is illustrated below:

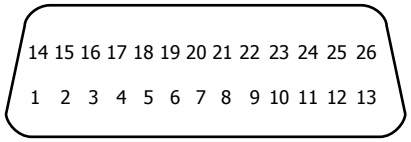


Figure 2: Multipurpose I/O-port

The multipurpose I/O-port integrates an "analog output" (Pins 1 – 8) and the "nurse call" (Pins 24 – 26). The following table shows the pin assignment of the multipurpose I/O-port:

	Pins	Signal	Description	
Analog Output	**1**	Pleth signal	Voltage: 0 – 1.05 V Parameter Range: min – max (not selectable)	
	2	Pleth ground		
	3	PR signal	Voltage: 0 – 1.05 V Parameter Range: 30-80, 30-125, 50-120, 100-250, 30-250 [bpm]	
	4	PR ground		
	5	SpO_2 signal	Voltage: 0 – 1.05 V Parameter Range: 0-100, 50-100, 70-100, 85-100 [%]	
	6	SpO_2 ground		
	7	PCO_2 signal	Voltage: 0 – 1.05 V Parameter Range: 10-50, 25-55, 25-75, 35-100, 60-140, 75-200, 120-200, 0-75, 0-100, 0-200 [mmHg] / 1.5-7.0, 3.5-7.5, 3.5-10.0, 4.5-15.0, 8-18.0, 10.0-27.0, 16.0-27.0, 0-10.0, 0-15.0, 0-27.0 [kPa]	
	8	PCO_2 ground		
	9 - 23	**Reserved**		
Nurse Call	**24**	Common lead for nurse-call relays 1 + 2		
	25 (+24)	Nurse call relay 1	active closed	**closes** when alarm sounds
	26 (+24)	Nurse call relay 2	active open	**opens** when alarm sounds

Table 11: Pin assignment, multipurpose I/O-port

Analog Output

The SDM provides analog voltage outputs for SpO_2, PCO_2, PR, and the Pleth Waveform on pins 1 - 8 of the mulitpurpose I/O-port. The output voltage represents a specific measured parameter's current value. Depending on the position of the V-Sign™ Sensor and/or the operation mode/status of the SDM the analog output is active or inactive (i.e. set to 0 Volt).

SDM Mode	Sensor Position (Status Message)	PCO_2	SpO_2	PR	Pleth
Monitoring Mode	**On Patient**	**Signal**	**Signal**	**Signal**	**Signal**
	On Patient ("SpO2 stabilizing")	**Signal**	0 Volt	0 Volt	**Signal**
	On Patient ("PCO2 stabilizing", "Change sensor membrane")	0 Volt	**Signal**	**Signal**	**Signal**
	Off Patient	0 Volt	0 Volt	0 Volt	**0.5 Volt**
	In Docking Station	0 Volt	0 Volt	0 Volt	0 Volt

Table 12: Analog data output signals

Note: In the "Neonatal" mode (PCO_2-only) or if the menu parameter "Measurement Settings/Enabled Parameters" is set to "PCO2" in the "Adult" mode the analog output for SpO_2, PR, and Pleth are permanently inactive (i.e. set to 0 Volt).

Note: In the SpO_2-only mode, i.e. if the menu parameter "Measurement Settings/Enabled Parameters" is set to "SpO2 PR" the analog output for PCO_2 is permanently inactive (i.e. set to 0 Volt).

Changing the parameter range for the analog outputs

The voltage differential varies proportionally from 0 to 1 volt as the pin's parameter varies over the selected parameter range. In the menu "Interfaces / Analog Outputs" it is possible to change the parameter range that is attributed to the 0 to 1 Volt output range for PCO_2, SpO_2, and PR. The selectable parameter ranges are indicated in Table 11.

Note: The voltage on a parameter's pin will be 0 Volt or 1 Volt if the parameter's current value is out of range, i.e. smaller than the minimum or bigger than the maximum of the selected parameter range, respectively. When changing the parameter range for a parameter ensure that the selected parameter range covers the expected values for this parameter.

Calibrating an instrument attached to the analog output of the SDM

Activating the menu function "Calibration Sequence" in the menu "Interfaces / Analog Outputs" causes for all parameters the output of 1 Volt during 60 seconds, followed by the output of 0 Volt during another 60 seconds. When the calibration sequence is running the current output voltage is indicated on the display.

Note: By pressing ENTER it is possible
a) to change from 1 Volt to 0 Volt (if output of 1 Volt is active)
b) to stop the calibration sequence (if output of 0 Volt is active)

Nurse Call

⚠ **WARNING:** The nurse call feature is inactive whenever the alarms of the SDM are muted.

⚠ **WARNING:** The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the SDM, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

The nurse call feature of the SDM works in conjunction with the nurse call system of your institution when the monitor activates an audible alarm. It duplicates audible alarms to the nurse call system of your institution, i.e. whenever an audible alarm of the SDM sounds, your institution's nurse call system is activated. The nurse call feature is accessed through the data port pins 24, 25 and 26 of the mulitpurpose I/O-port.

The nurse call interface of the SDM is relay-based and is available when the SDM is operating either on AC power or on battery power. The remote location is signaled anytime there is an audible alarm. If the audible alarm has been muted, the nurse call function is also inactive. The nurse call function can be switched on or off in the menu "Interface Settings".

Pins 24 and 25 provide a relay that closes when an alarm is sounding on the monitor. Pins

24 and 26 provide a relay that opens when an alarm is sounding. Pin 24 is a common lead for both relays.

⚠ **WARNING:** The nurse call function must be tested before each application.

Testing the Nurse Call function

The nurse call feature should be tested whenever setting up the SDM in a location that uses this nurse call. One way to test the nurse call function is to create an alarm condition (e.g. sensor disconnected) and verify that your facility's nurse call system is activated.

Serial Data Port (RS-232)

The serial data port (RS-232) of the SDM is used to communicate with external data collection systems such as personal computers, multiparameter bedside monitors and data loggers. The serial data port (RS-232) is located on the rear panel of the SDM (17). The pin layout of the serial data port (RS-232) is illustrated below:

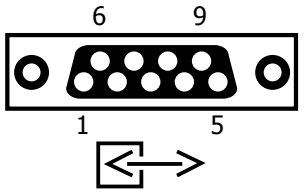


Figure 3: Serial data port (RS-232)

The following table shows the pin assignment of the serial data port (RS-232):

Pin(s)	Signal
1	Reserved
2	Transmitted data (Tx)
3	Received data (Rx)
4	Reserved
5	Signal ground
6-9	Reserved

Table 13: Pin assignment of the serial data port (RS-232)

Communication Protocols

Through the menu parameter "Interfaces / Serial Interface / Protocol" the following serial communication protocols are selectable:

Philips VueLink

Select this protocol to enable data transfer from the SDM to Philips Patient Monitoring Systems via the "Philips VueLink Open Interface" (resolution = 0.1 mmHg). PCO_2 values > 101 mmHg will NOT be transmitted. For details please refer to the "VueLink Installation Manual".

Philips VueLink 2

Select this protocol to enable data transfer from the SDM to Philips Patient Monitoring Systems via the "Philips VueLink Open Interface" (resolution = 1 mmHg). PCO_2 values up to 200 mmHg will be transmitted. For details please refer to the "VueLink Installation Manual".

Spacelabs Flexport

Select this protocol to enable data transfer from the SDM to Spacelabs Healthcare monitors via the "Flexport System Interface". For details please refer to the "Flexport Interface Manual".

SenTec Datalogger

Select this protocol for on-line data recording of SDM data on the removable Multi-Media card (memory card) of the SenTec Datalogger.

Note: The SenTec Datalogger is a microprocessor controlled recording device that is indicated for continuous recording of the data of the SenTec Digital Monitor (SDM). A 64 Mb Multi-Media Card has the capacity to store approx. 240 hours SDM data. For details please refer to the "Instruction Manual for the SenTec Datalogger".

SenTecLink

SenTecLink enables bidirectional communication and data transfer between the SDM and external applications such as other devices or PC based applications. An example of an external application is "V-STATS™", SenTec's PC based data download and analysis software.
In its default configuration SenTecLink

a) continuously outputs on-line (real-time) data of the SDM
b) constantly checks for an incoming command sent by a bench. Once the SDM recognizes an incoming command it sends the corresponding command response. In particular it is possible to activate the download of the data stored in the internal memory of the SDM by sending an appropriate command.

Serial Port Settings

The following communication protocol parameters should be set at the receiving device:

Parameter	Values
Bits per second	User-selectable: 115'200, 57'600, 38'400, 19'200
Data bits	8
Parity	None
Stop bits	1
Flow control	None

Table 14: Serial Port Settings

Activation of SenTecLink / Selection of Baud rate

To activate the communication protocol SenTecLink and to select the desired baud rate proceed as follows:

- Set the menu parameter "Interface/Serial Interface/Protocol" to "SenTecLink"
- Select the desired baud rate in the menu parameter "Interfaces/Serial Interface/ Baud rate (SenTecLink)"

SenTecLink: On-line Data Output

Date flow

Output of Data lines	One data line per second
Output of heading lines	1) Immediately after activation of the protocol "SenTecLink" 2) Every 50 data lines 3) Immediately after changing the PCO_2 units from "mmHg" to "kPa" or vice versa.

Table 15: SenTecLink: Data flow

Heading and Data lines content

SenTecLink's on-line data output exports the data in an ASCII TSV (tab-separated values) format.

Main heading line		***SENTEC DIGITAL MONITORING ON-LINE DATA***
Monitor info heading line	Column 1 Column 2 Column 3 Column 4	Monitor:<value> *serial number of monitor* MPB-SW:<value> *software version of MPB* SMB-SW:<value> *software version of SMB* Patm[mmHg]:<value> **or** Patm[hPa]:<value> *measured barometric pressure*
Sensor info heading line	Column 1 Column 2 Column 3 Column 4 Column 5 Column 6	Sensor:<value> *sensor model* SN:<value> *serial number of sensor* SW:<value> *software version of sensor* T[°C]:<value> *SET temperature of sensor* PID: <value> *patient ID* <value> *patient type (adult or neonatal)*
Data column heading lines	Column 1 Column 2 Column 3 Column 4 Column 5	Date&Time[yyyy-mm-dd hh:mm:ss] SpO2[%]<low limit>:<high limit> PCO2[mmHg]<low limit>:<high limit> **or** PCO2[kPa]<low limit>:<high limit> PR[bpm]<low limit>:<high limit> Status
Data lines	Column 1 Column 2 Column 3 Column 4 Column 5	<date><time> <SpO2 value><Limit violation>[a] <PCO2 value><Limit violation>[a] <PR value><Limit violation>[a] <code>[b]

Table 16: SenTecLink: Heading and Data lines content

[a] A plus sign ("+") behind a measured value indicates that the upper alarm limit of the respective parameter has been violated. A minus sign ("-") behind a measured value indicates that the lower alarm limit of the respective parameter has been violated.

[b] Output of up to 4 status codes; for explanation of the status codes refer to the sub-section "Status Messages / Status Codes"

SDM Mode	Sensor Position (Status Message)	PCO_2	SpO_2	PR	Pleth
Monitoring Mode	**On Patient**	**Value**	**Value**	**Value**	n.a.
	On Patient ("SpO2 stabilizing")	**Value**	i*	i*	n.a.
	On Patient ("PCO2 stabilizing")	i*	**Value**	**Value**	n.a.

Monitoring Mode	**On Patient** ("Change sensor membrane")	i	**Value**	**Value**	n.a.
	Off Patient	—	—	—	n.a.
	In Docking Station	**Value**	—	—	n.a.
"Demo Mode"	**On Patient** (not applicable, the Demo Mode automatically deactivates if the sensor is applied to the patient)	n.a.	n.a.	n.a.	n.a.
	Off Patient ("DEMO MODE")	**Value**	**Value**	**Value**	n.a.
	In Docking Station ("DEMO MODE")	**Value**	—	—	n.a.

Table 17: SenTecLink: Online Data Output in various situations.

Note: In the "Neonatal" mode (PCO_2-only) or if the menu parameter "Measurement Settings/Enabled Parameters" is set to "PCO2" in the "Adult" mode the on-line output for SpO_2, PR is permanently set to "i".

Note: In the SpO_2-only mode, i.e. if the menu parameter "Measurement Settings/Enabled Parameters" is set to "SpO2 PR" the on-line output for PCO_2 is permanently set to "i".

SenTecLink: Download of data stored in the internal memory

The SDM automatically stores data line by line according to the FIFO (First In, First Out) principle. The data stored in the internal memory of the SDM can be downloaded by external applications that send the appropriate commands. An example is "V-STATS™", SenTec's PC based data download and analysis software.

By using "V-STATS" (PC-Software for the SDM) it is furthermore possible to select the data recording interval, and hence the memory capacity, as indicated in the following table:

Data Recording Interval [seconds]	Memory Capacity [days]	
	Volatile memory (RAM)	Non-volatile memory (FLASH)
1	**0.5**	**1.5**
2	**1.0**	**3.0**
4 (Factory Default)	**2.0**	**6.0**
8	**4.0**	**12.0**

Note: The data recording interval can only be changed by using "V-STATS" (PC-Software for the SDM), i.e. it can NOT be changed in the menu of the SDM. The currently active data recording interval, the free and total memory capacity are displayed in the menu "Trend Data" along with the memory type (volatile / non-volatile) used in your SDM.

Note: The data stored in the internal memory of the SDM are deleted if the data recording interval is changed.

Note: If the SDM is switched off and on again, the selected data recording interval will be retained.

Note: If the internal memory of your SDM is volatile, the history data will be lost if the SDM is switched off. A SDM with a volatile memory must be turned on to keep the memory active.

Note: The PCO2 data are output using the unit that is active on the SDM when activating the data download.

Maintenance of the SDM

To guarantee continuous performance, safety, and reliability of the equipment maintenance procedures and checks have to be performed regularly. The maintenance of the SDMS is subdivided into "Cleaning and Disinfection", "Routine Checks", and "Safety & Functionality Tests".

The present section deals with "Cleaning and Disinfection" and "Routine Checks". "Instructions for shipment of the SDMS" are provided at the end of this section.

Please refer to the "Service Manual" and the "Repairs and Service Manual" for detailed information on "Safety & Functionality Tests", as well as for instructions for service and repairs.

Cleaning and Disinfection

⚠ **WARNING:** Before cleaning the monitor, always switch it off and disconnect it from AC power.

! **CAUTION:** Plugs and connectors have to be kept clean and dry at all times. Do not expose the SDM to heavy moisture and do not allow any fluids to enter the SDM.

! **CAUTION:** Do not use any cleaning and disinfection procedures other than those recommended here.

! **CAUTION:** Do not sterilize any parts of the SDM by irradiation, steam or ethylene oxide.

The directions for cleaning and disinfection vary from hospital to hospital. In case of doubt consult your hygiene department.
SenTec recommends the following cleaning and disinfection agents:

- WEBCOL® Pads, Medium Size, containing 70% isopropanol (KENDALL, Tyco/ Healthcare)
- KLENZYME® (Steris)
- CIDEX OPA® (Johnson and Johnson)

Refer to the instructions for use of the respective manufacturer for preparation, application and disposal of the cleaning agents.

Surface Cleaning

Use the following procedure to clean the SDM and the AC power cable :

1. Carefully wipe all surfaces of the SDM with a WEBCOL Pad.
2. Wipe all surfaces of the SDM with a gauze pad dampened in sterile or distilled water.
3. Blot dry, or carefully swab all surfaces of the SDM with a clean, dry gauze pad.

Low Level Cleaning and Disinfection

Use the following procedure to clean and disinfect the SDM and the AC power cable:

1. Wipe the SDM with a gauze pad dampened in KLENZYME, wait 5 min.
2. Wipe the SDM with a gauze pad dampened in sterile or distilled water.
3. Blot dry, or carefully swab all surfaces with a clean, dry gauze pad.
4. Carefully wipe all SDM surfaces with a WEBCOL Pad, allow to dry.

High Level Cleaning and Disinfection

Use the following procedure to clean and disinfect the SDM and the AC power cable thoroughly:

1. Wipe the SDM with a gauze pad dampened in KLENZYME, wait 5 min.
2. Wipe the SDM with a gauze pad dampened in sterile or distilled water.
3. Blot dry, or carefully swab all surfaces with a clean, dry gauze pad.
4. Carefully wipe all SDM surfaces with a WEBCOL Pad, allow to dry.
5. Wipe the SDM with a gauze pad dampened in CIDEX OPA, wait 12 min.
6. Wipe the SDM 3 times with a gauze pad dampened in sterile or distilled water (renew gauze pad after each wiping cycle).
7. Blot dry, or carefully swab all surfaces with a clean, dry gauze pad.
8. Carefully wipe all SDM surfaces with a WEBCOL Pad, allow to dry.

Keep plugs and connectors meticulously clean and dry. Do not allow any liquid to enter the SDM. If the SDM becomes wet accidentally, it should be wiped dry externally and allowed to dry thoroughly before use. Do not subject the SDM to extreme moisture. Such exposure may cause inaccurate performance or device failure.
Carefully clean the gasket of the SDM Docking Station using a cotton swab (Q-Tip) with 70% isopropanol which does not lose any fibers or threads. Any particles on the gasket or sensor might prevent a tight fit between the gasket and the sensor and, hence, cause a gas leak.

Note: For cleaning of the V-Sign™ Sensor refer to the respective Directions for Use.

Routine Checks/Procedures

To guarantee continuous performance, safety and reliability of the SenTec Digital Monitoring System, basic maintenance procedures and checks have to be performed regularly. This sub-section covers routine checks for the V-Sign™ Sensor, the SenTec Digital Monitor, the SDM´s Docking Station, the Digital Monitor Extension Cable, the AC power cord and the Service Gas.

Please check the expiration dates of the V-Sign™ Disposable Set, the Sensor Gel, the Ear Clip, the Multi-Site Attachment Ring and the Service Gas monthly. Replace expired products!

	V-Sign™ Sensor	
Check/ Procedure	**When**	**Description**
Cleaning sensor body	Each time before inserting into Docking Station	Refer to the Directions for Use of the V-Sign™ Sensor.
Cleaning sensor cable	Monthly	Refer to the Directions for Use of the V-Sign™ Sensor.
Disinfection	At your discretion	Refer to the Directions for Use of the V-Sign™ Sensor.
Visual inspection of the sensor membrane	Before each measurement Before each calibration	Make sure the sensor is not affected by loose fit of the membrane, trapped air under the membrane, or dried-up electrolyte (white appearance of the membrane). If needed change the membrane.
Visual inspection of sensor body and cable	Monthly	Check the sensor body and sensor cable for breaks or damages. Check the sensor cable plug and its connectors for damages.
Labeling	Monthly	Check presence and legibility of the label with the serial number (on the plug of the sensor cable).
Sensor LED	Weekly	Verify that the LEDs of the sensor emit red light (when switched on).
Function test: SpO_2, PR, PCO_2	Monthly	Calibrate the sensor and apply it to a healthy person. Compare SpO_2 and PR readings against the readings of a reference pulse oximeter. Verify, that the PCO_2 readings equilibrate (stabilize) within 3 to 10 minutes and are within 33 to 47 mmHg after stabilization.
PCO_2 Sensitivity test	Monthly	Test the PCO_2 sensitivity as follows: · Activate the display of the PCO2 calibration curve · Following a calibration, expose the sensor for 3 minutes to ambient air. · Reinsert the sensor into the Docking Station. The first displayed PCO_2 value should be at least 30 mmHg (4.0 kPa) lower than after calibration. · If this difference is not reached, change the membrane of the sensor. After a renewed missing of this difference, consult qualified service personnel.
Sensor temperature surveillance	Monthly	Connect the sensor to the SDM and switch-on the SDM. Immerse the sensor into a water bath of approximately 47°C. Verify that the sensor's LEDs switch off, a low priority alarm starts to sound and that the message "Sensor fault" or "Temp. limiter active" displays.

Table 18: V-Sign™ Sensor - Routine Checks/Procedures

	SenTec Digital Monitor	
Check/ Procedure	**When**	**Description**
Service	Annually	Qualified service personnel shall perform annual service as outlined in the Service Manual.
Cleaning	Monthly	Refer to the section "Cleaning and Disinfection" of this manual.
Disinfection	At your discretion	Refer to the section "Cleaning and Disinfection" of this manual.
Visual inspection	Weekly	Visually check the entire SDM for possible damages. If you detect any damage, contact qualified service personnel.

Labeling	Monthly	Check presence and legibility of all labels. Refer to the sub-section "SDM Symbols" of this manual.
POST	Monthly	Connect the SDM to AC power. Turn it off and then on again. Check the activation of the display, the LED indicators and the audible signals during the power-on self-test. For details refer to the sub-section "Power-On Self-Test" of this manual.
Display/LED's (POST)	Biannually	During the POST, the Alarm Mute Indicator (yellow LED) and the ON/OFF Indicator (green LED) are activated. The AC Power/Battery Indicator LED is lit yellow (battery charging in progress) or green (battery charging completed). Control the display for inactive pixels during the POST: the display background should be uniformly grey.
Speaker (POST)	Biannually	Check the activation of the speaker during the POST. Refer to the sub-sections "Audible Indicators" and "Power-On Self-Test" of this manual.
Clock Settings	Weekly	Verify that the clock settings are correct. If necessary, adjust the clock in the SDM Menu "System Settings/Date/Time" or by using "V-STATS" (PC-Software for the SDM).
Fan	Biannually	If the SDM is connected to AC power, the fan shortly activates when switching on the SDM. The fan must rotate freely and without causing unusual noises. If you blow into the fan slits on the rear panel when the fan is off, the fan has to rotate.
Barometric Pressure	Monthly	Check the barometer of the SDM against a known calibrated barometer. In case of deviations bigger than ± 5 mmHg (0.7 kPa) contact qualified service personnel.
High priority alarm	Biannually	Apply the sensor to a test person. Adjust the SpO_2 high limit such as the SpO_2 values violate the SpO_2 high limit. Verify that the SpO_2 value is flashing with a frequency of about 3 Hz and that a high priority alarm sounds as described in the sub-section "Audible Indicators" of this manual.
Low priority alarm	Biannually	Cause a low-priority alarm situation. (e.g. disconnect the sensor). Verify that the respective status message displays and that a low priority alarm sounds as described in the sub-section "Audible Indicators" of this manual.
Nurse Call	Monthly Upon set-up	Refer to the sub-section "Nurse Call" of this manual.

Table 19: SenTec Digital Monitor - Routine Checks/Procedures

	SDM Docking Station	
Check/ Procedure	**When**	**Description**
Cleaning	Weekly	Refer to the section "Cleaning and Disinfection" of this manual. Clean the gasket of the SDM Docking Station using a cotton swab (Q-Tip) with 70% isopropanol. Take care not to damage the gasket or to leave any fibers or threads. Let the gasket dry completely before you use the SDM Docking Station again.
Disinfection	At your discretion	Refer to the section "Cleaning and Disinfection" of this manual. Make sure that the gasket of the SDM Docking Station is completely dry and is well embedded in its notch after disinfection and before using the SDM again.
Visual inspection	Monthly	Inspect the Docking Station door and the gasket for mechanical damages. The closing mechanism must properly lock in place.

Table 20: Docking Station - Routine Checks/Procedures

Digital Monitor Extension Cable		
Check/ Procedure	**When**	**Description**
Cleaning	Monthly	Refer to the Directions for Use of the V-Sign™ Sensor.
Disinfection	At your discretion	Refer to the Directions for Use of the V-Sign™ Sensor.
Visual inspection	Monthly	Check the Digital Monitor Extension Cable for mechanical or functional damages. Defective cables must be replaced by original replacement parts.
Labeling	Monthly	Check presence and legibility of the label with the lot number (on the plug of the cable).

Table 21: Digital Monitor Extension Cable - Routine Checks/Procedures

AC power cord		
Check/ Procedure	**When**	**Description**
Cleaning	At your discretion	Refer to the section "Cleaning and Disinfection" of this manual.
Disinfection	At your discretion	Refer to the section "Cleaning and Disinfection" of this manual.
Visual inspection	Monthly	To avoid electrical shock remove the AC power cord from the SDM before visual inspection. Check the AC power cord for breaks or damages of the isolation. Check the AC power cord connectors for damages.

Table 22: AC power cord - Routine Checks/Procedures

Service Gas		
Check/ Procedure	**When**	**Description**
Visual inspection	Weekly	The Service Gas bottle is a pressurized container. Inspect for scratches or dents, replace if damaged.

Table 23: Service Gas - Routine Checks/Procedures

Service

⚠ **WARNING:** The cover of the SDM should be removed only by SenTec authorized service personnel. There are no user-serviceable parts inside the SDM.

The SDM must be controlled annually by qualified service personnel (using the Service Manual for the SDM). If service or instrument repairs are necessary contact SenTec authorized service personnel or your local SenTec representative.

Before the annual control you must clean and disinfect the SDM as described in the section "Cleaning and Disinfection".

Instructions for Shipment of the SDMS

Please contact your local SenTec representative before returning any material. Unless covered by warranty, shipment costs, costs for repair and service work will be billed to the sender.

The following instructions apply to all shipments of SDMS or any part of it to qualified / SenTec authorized service personnel or to your local SenTec representative:

1. Please return the SDM with AC power cord and/or the V Sign™ Sensor, but without any accessories such as the V Sign™ Disposable Set, the Sensor Gel, the Ear Clip, the Multi-Site Attachment Ring or the Service Gas.
   Important: do not ship Service Gas bottles together with the SDM. Gas bottles have to be declared as "dangerous goods", a special IATA form is therefore required and special packing instructions apply.

2. Devices must be properly disinfected. For disinfection instructions please refer to the Directions for Use of the V-Sign™ Sensor and the sub-section "Cleaning and Disinfection" in the SDM's Technical Manual. The "Certificate of Disinfection" and, if applicable, the "Repair Form" are to be completed by the responsible person and have to be shipped together with the SDMS.

3. If you send back electronic parts, make sure to follow applicable ESD precautions.

4. Items must be shipped in the original packaging or in other packing providing the same degree of protection. Use sanitized packing material only.

Certificate for Disinfection

All items must be disinfected before shipment.
This certificate serves as proof of disinfection. Any items arriving at qualified/ SenTec authorized service personnel or your local SenTec representative lacking this certificate or being accompanied by an improperly issued certificate will be disinfected at the sender's expense without prior notice. The sender will be held liable for any harm attributed to improper disinfection.

For disinfection instructions please refer to the Directions for Use of the V-Sign™ Sensor and the sub-section "Cleaning and Disinfection" in the SDM's Technical Manual.

Items in shipment

SenTec Digital Monitor, serial No. (label on rear pannel): _____

V-Sign™ Sensor, serial No. (label on connector): _____

Complete this table to identify the items that have been disinfected.

Item	Not shipped	Disinfected
SenTec Digital Monitor	☐	☐
SDM Docking Station (incl. gasket)	☐	☐
V-Sign™ Sensor (incl. cable)	☐	☐
Digital Monitor Extension Cable	☐	☐
AC power cord	☐	☐
	☐	☐
	☐	☐

Organization _____

Location _____

_____

Disinfected by (name) _____

Place, date _____

Signature _____

Important: This document has to remain with the disinfected items until returned to sender.

Repair Form

Send this document together with any defective part. Describe the problem and possible causes you found during your tests. Please use the troubleshooting list provided in the SDM's Technical Manual to identify the problem (PXXXX number) and the possible cause. Fill in the serial number and the hard- and software specific information of the complete SDMS (monitor and sensor) to be repaired, even if you send back only one component of the system. You will find this information in the SDM's sub-menu "System information". The serial number of the monitor is provided on its rear panel.

SenTec Digital Monitor, serial No.: _____
SMB Hardware Version: _____
SMB Software Version: _____
MPB Hardware Version: _____
MPB Software Version: _____

V-Sign™ Sensor, serial No.: _____
Sensor Hardware Version: _____
Sensor Software Version: _____

Pos.	Part designation	Comment: problem (PXXXX number)* / possible cause
1		
2		
3		
4		

*PXXXX number according to troubleshooting list in the Technical Manual for the SDM.

Organization _____

Location _____

_____

Name _____

Place, date _____

Signature _____

Troubleshooting

This section describes problems, possible causes and the recommended operator actions. The following groups of problems are covered:

- Troubleshooting PCO_2 monitoring
- Troubleshooting SpO_2 / PR monitoring
- Sensor specific troubleshooting
- Sensor application specific troubleshooting
- SDM specific troubleshooting
- Docking Station specific troubleshooting

If a problem persists after the recommended operator action(s), please contact qualified /SenTec authorized service personnel or your local SenTec representative. Please use the troubleshooting list to identify the PXXXX number. If you need to ship the SDMS or any part of it to qualified/ SenTec authorized service personnel or your local SenTec representative please fill in the PXXXX number in the Repair Form and send the Repair Form together with any defective part.

Troubleshooting PCO_2 monitoring

Note: When comparing PCO_2 values displayed by the SDM against PCO_2 values obtained from arterial blood gas (ABG) analysis, pay attention to the following points:

- Carefully draw and handle blood samples.
- Blood sampling should be performed in steady state conditions.
- The PCO_2 value obtained from ABG analysis has to be compared to the SDM's PCO_2 at the time of blood sampling.
- The PCO_2 values displayed by the SDM are automatically corrected to 37°C (regardless of the patient's core temperature). When performing the ABG analysis make sure to properly enter the patient's core temperature into the blood gas analyzer. Use the blood gas analyzer's "37°C-PCO_2" value to compare with the SDM's PCO_2 values.
- Verify proper operation of the blood gas analyzer. Periodically compare the blood gas analyzer's barometric pressure against a known calibrated reference barometer.

Problem	Possible Cause	Recommended action(s)
P0100 PCO_2 values increase very slowly / not stable 20 minutes after sensor application	Sensor loosely attached, air gap/leak between sensor and skin; no Sensor Gel	Gently squeeze the Ear Clip / rotate the sensor in the Multi-Site Attachment Ring to distribute the Sensor Gel evenly between the sensor surface and skin. If needed, reapply the sensor securely using one drop of Sensor Gel. For earlobe placement ensure to completely cover the sensor surface with the patient's earlobe. Gently pull on the patient's earlobe when applying the sensor. **Note:** You may use clean tap water instead of Sensor Gel.
	Sensor too slow	Refer to P0304.
P0101 PCO_2 too low	Sensor loosely attached, air gap/leak between sensor and skin; no Sensor Gel	Refer to P0100.
	PCO_2 part of the sensor unstable (causing drift)	To stabilize the sensor insert it into the Docking Station with the monitor switched on. **Note:** After changing the sensor membrane; prolonged ambient air exposure of > 30 minutes; and after switching on the sensor/SDM; please leave the sensor in the Docking Station for at least 4 hours with the SDM switched on.
	Wrong calibration gas	Verify that SenTec Service Gas is used.
	Service Gas expired	Replace gas bottle with a new gas bottle (verify the expiration date indicated on the gas bottle label).
	Wrong/instable barometric pressure during calibration	Verify that the barometric pressure reading of the SDM is stable during calibration and does not deviate from a known calibrated reference barometer by more than 5 mmHg (0.7 kPa). Otherwise contact qualified service personnel.
	PCO_2 sensitivity of the sensor too low	Test the PCO_2 sensitivity as follows: · Activate the display of the PCO2 calibration curve. · Following a calibration, expose the sensor for 3 minutes to ambient air. · Reinsert the sensor into the Docking Station. The first displayed PCO_2 value should be at least 30 mmHg (4.0 kPa) lower than after calibration · If this difference is not reached, change the membrane of the sensor and repeat the test.

Problem	Possible Cause	Recommended action(s)
		After a renewed missing of this difference, consult qualified service personnel.
	Significant PCO_2 drift	Verify that the sensor is not affected by loose fit of the membrane, trapped air under the membrane. If needed perform an unrequested membrane change (activate the menu "Membrane Change"). After membrane change calibrate the sensor and allow the PCO_2 part of the sensor to stabilize for 4 hours. If no change of the sensor membrane is needed allow the sensor to stabilize for an additional 2 – 3 hours. If problem persists contact qualified service personnel.
P0102 PCO_2 too high	Hypoperfused measurement site	Evaluate the patient status. Shock, low cardiac index, hypothermia and inadequate local vasodilatation are physiological limitations of the method. Avoid any mechanical pressure / stress on the measurement site: · Do not allow the patient to put the head on the ear-lobe. · Do not pull the cable. · Secure cable with adhesive tape and Clothing Clip.
	Improper V-Sign™ Sensor application (wrong measurement site)	Verify that the sensor is not applied on sites other than those recommended in the Instruction Manual for the SDMS. If necessary re-apply the sensor on a recommended site.
	PCO_2 part of the sensor unstable (causing drift)	Refer to P0101
	Wrong calibration gas	Refer to P0101
	Service Gas expired	Refer to P0101
	Docking Station gas leak	Insert the sensor into the Docking Station and observe the system during 20 minutes. When the sensor is in the Docking Station, the SDM evaluates the integrity of the Docking Station system. If a failure occurs, a low priority alarm sounds and the message "Gas leak inDS" is displayed. In this case carefully inspect the door and gasket.
		Clean the Docking Station gasket and sensor with a cotton swab. Remove any residual threads and fibers then recalibrate the sensor. Observe the system during 20 minutes to detect any reoccurrence. If the problem persists contact qualified service personnel.
	Wrong/instable barometric pressure during calibration	Refer to P0101.
	PCO_2 sensitivity of the sensor too low	Refer to P0101.
	Significant PCO_2 drift	Refer to P0101.
P0103 PCO_2 suddenly changes (decreases)	Sensor loosely attached, air gap/leak between sensor and skin; no Sensor Gel	Refer to P0100.
	Adhesive pad of Ear Clip / Multi-Site Attachment Ring does not stick any more	Reapply the sensor with a new Ear Clip / Multi-Site Attachment Ring
	Electrocautery, HF surgery, defibrillation	The values will come back to normal after electrocautery, HF surgery or defibrillation.

Table 24: Troubleshooting PCO_2 Monitoring

Troubleshooting SpO_2 and PR monitoring

Problem	Possible Cause	Recommended action(s)
P0200 SpO_2 and/or PR too low or too high	Venous pooling (e.g. Trendelenburg position)	Limitation of the method. For earlobe placement of the sensor avoid conditions where the head is positioned lower than the heart.
	Cardiac arrhythmias	Limitation of the method.
	Inadequate local blood flow at the measurement site	Evaluate the patient status. Shock, low cardiac index, inadequate local vasodilatation are physiological limitations of the method.

Problem	Possible Cause	Recommended action(s)
		Avoid any mechanical pressure / stress on the measurement site: · Do not allow the patient to put the head on the earlobe. · Do not pull the cable. · Secure cable with adhesive tape and Clothing Clip.
	Electrocautery, HF surgery, defibrillation	The values will come back to normal after cautery, HF surgery or defibrillation.
	Improper V-Sign™ Sensor application (wrong measurement site)	For SpO_2/PR monitoring the sensor must be applied to the earlobe. Verify that the membrane of the V-Sign™ Sensor is completely covered by the patient's earlobe. If not, reapply the sensor (if necessary on the opposite earlobe or on the front side of the same earlobe).
	Artifacts due to patient movements	Reapply the V-Sign™ Sensor as described in the Directions for Use of the Ear Clip and secure the cable with adhesive tape and the Clothing Clip to ensure a motion-insensitive sensor fixation.
	Measurement is influenced by strong ambient light	Shield V-Sign™ Sensor from strong ambient light (e.g. lamps). Verify that the membrane of the V-Sign™ Sensor is completely covered by the patient's earlobe.
	Dysfunctional hemoglobin	Physiological limitation of the method. In patients with high carboxyhemoglobin levels (e.g. smokers) functional saturation measured with a pulse oximeter will overestimate functional saturation determined with a CO-oximeter.
	Too much Sensor Gel causing light shunting	Remove V-Sign™ Sensor. Clean sensor and earlobe with an alcohol pad. Reapply the sensor using only one drop of Sensor Gel.
	Intravascular dyes	Limitation of the method. Dyes used as tracer, contrast medium, etc. may absorb light at the same wavelength as the one used for pulse oximetry measurements.

Table 25: Troubleshooting SpO_2 and PR monitoring

Sensor Specific Troubleshooting

Problem	Possible Cause	Recommended action(s)
P0300 Sensor Fault is displayed	Sensor temperature too high (e.g. caused by heat sources such as warming lamps/blankets)	Shield V-Sign™ Sensor from heat source. Switch the SDM off and on again. If problem persists contact qualified service personnel.
P0301 Sensor LEDs not illuminated	V-Sign™ Sensor or SDM defective	Switch the SDM off and on again. If problem persists contact qualified service personnel.
P0302 White spots on the membrane	Sensor affected by defective membrane, trapped air under the membrane	Perform an unrequested membrane change (activate the menu "Change membrane"). Confirm the membrane change as requested by the SDM. After membrane change calibrate the sensor and allow the PCO_2 part of the sensor to stabilize for 4 hours (sensor in Docking Station with SDM switched on).
P0303 After each calibration the SDM requests to change the membrane	· No membrane · Defective membrane (holes or scratches) · Old membrane	Change the membrane and confirm as requested by the SDM. After membrane change calibrate the sensor. If problem persists contact qualified service personnel.
	V-Sign™ Sensor too slow	Refer to P0304
	Docking Station door is not closed properly	Close the Docking Station door properly. If problem persists contact qualified service personnel.
	V-Sign™ Sensor defective	Switch the SDM off and on again. If problem persists contact qualified service personnel.
P0304 Calibration aborted after 14 min	V-Sign™ Sensor too slow.	Change membrane of sensor. Then calibrate the sensor. If problem persists contact qualified service personnel.

Problem	Possible Cause	Recommended action(s)
P0305 V-Sign™ Sensor calibration does not start	Service Gas bottle empty	Use a new Service Gas bottle and install it.
	V-Sign™ Sensor temperature is too low	Wait until the sensor temperature is less than 0.5 °C below the SET temperature. If problem persists contact qualified service personnel.
P0306 Temp. limiter active is displayed	V-Sign™ Sensor temperature is enhanced because of warming lamps or electric blankets	Shield V-Sign™ Sensor from heat. If problem persists contact qualified service personnel.
	Electrocautery, HF surgery, defibrillation	The values will come back to normal after cautery, HF surgery or defibrillation.
P0307 Sensor is blocked in the Membrane Change Tool	Membrane Change Tool is blocked	Open Membrane Change Tool according to the Directions for Use of the V-Sign™ Disposable Set. If problem persists contact qualified service personnel.

Table 26: Sensor Specific Troubleshooting

Sensor Application Specific Troubleshooting

Problem	Possible Cause	Recommended action(s)
P0400 V-Sign™ Sensor cannot be applied correctly at the inside of the earlobe.	Earlobe too small or cartilaginous	Reposition the V-Sign™ Sensor (e.g. on the opposite earlobe or on the front side of the same earlobe). It might be necessary to gently pull on the earlobe so that the V-Sign™ Sensor surface is completely covered by the earlobe. Apply the sensor on an alternate measurement site with a Multi-Site Attachment Ring (PCO_2-only monitoring).
	Multiple-pierced earlobe	Reapply the V-Sign™ Sensor on the opposite earlobe or try to fill the holes with Sensor Gel. Apply the sensor on an alternate measurement site with a Multi-Site Attachment Ring (PCO_2-only monitoring).
P0401 Adhesive tape of Ear Clip or Multi-Site Attachment Ring does not attach properly to skin	Site not clean/hairy	Remove sensor. Clean Site/remove hairs if necessary. Dry site and reapply sensor using a new Ear Clip/Multi-Site Attachment Ring.
	Wet adhesive tape	Remove sensor. Dry site and reapply sensor using a new Ear Clip/Multi-Site Attachment Ring. Avoid wetting the adhesive tape.
	Ear Clip/Multi-Site Attachment Ring expired	Remove sensor. Dry site and reapply sensor using a new Ear Clip/Multi-Site Attachment Ring. Verify the expiration date indiated on the respective package label.

Table 27: Sensor Application Specific Troubleshooting

SDM Specific Troubleshooting

Problem		Recommended action(s)
P0500 SDM not operational, SDM LEDs not illuminated	SDM switched off SDM not connected to mains and low battery	Switch on SDM. Connect the SDM to the mains. Allow battery to charge.
	Mains power supply defective	Choose another mains power supply for connecting the SDM.
	SDM defective	Switch the SDM off and on again. If problem persists contact qualified service personnel.
P0501 Display is dark, AC Power/Battery indicator (green/yellow LED) illuminated, ON/OFF indicator is off	SDM switched off	Switch on SDM. If problem persists contact qualified service personnel.

Problem	Possible Cause	Recommended action(s)
P0502 100% charged battery discharged after less than 3 h	Battery defective	Contact qualified service personnel.
P0503 Display is dark, ON/OFF indicator is illuminated	SDM in Sleep mode	Press any button. If the problem persists switch the SDM off and on again. If problem persists contact qualified service personnel.
P0504 Display is not readable (dark)	Brightness not adjusted correctly.	Switch the monitor off and on again. Then readjust the brightness.
	SDM defective	Switch the SDM off and on again. If problem persists contact qualified service personnel.
P0505 POST screen does not disappear	POST failed	Write down the Error code, switch the SDM off and on again. If problem persists contact qualified service personnel.
P0506 SDM does not react if any button is pressed	SDM defectiv	Contact qualified service personnel.
P0507 Clock shows wrong time and date after each restart.	Low internal battery	Contact qualified service personnel.
P0508 Barometric pressure is too low/high	Barometer chip defective	Verify the SDM's barometric pressure with a known calibrated reference barometer. The difference should be within 5 mmHg (0.7 kPa). If the problem persists contact qualified service personnel.

Problem	Possible Cause	Recommended action(s)
P0509 Fan is noisy	Fan defective or polluted	Contact qualified service personnel.
P0510 Fan is blocked	Fan defective or polluted	The fan has to be able to rotate freely. If you blow into the fan slits on the rear panel of the SDM, the fan has to rotate. If problem persists contact qualified service personnel.
P0511 No sound	Audible alarm is silenced	Audible alarm signals can be silenced for 1 minute, 2 minutes or permanently with the Alarm Mute Button and Alarm Mute Reminder is set to OFF. Push the Alarm Mute Button.
	Volume is on minimum	Adjust the volume in the menu "Alarm Settings". If problem persists contact qualified service personnel.
P0512 It is not possible to connect the mains power cord in the SDM AC power connector	AC Power Cord is defective	Replace the AC Power Cord.
	Power Entry Module defective	Contact qualified service personnel.
P0514 Wrong or no analog output	SDM defective	Contact qualified service personnel.
P0515 No communication over RS-232	SDM defective	Contact qualified service personnel.
P0516 No alarm on speaker, nurse cal	Audible alarm is muted	Audible alarm signals can be muted for 1 minute, 2 minutes or permanently with the Alarm Mute Button Push the Alarm Mute Button.

Problem	Possible Cause	Recommended action(s)
P0516 No alarm on speaker, nurse cal	SDM defective	Contact qualified service personnel.
P0517 Gas Level Indicator shows wrong indication	Gas level indicator shows wrong results	Repeat the test with the same sensor connected to the same SDM using the Docking Station of another SDM (Both SDMs need to be switched on). Make sure the sensor is in the Docking Station and the door is closed correctly, wait 5 seconds.
	SDM defective	Contact qualified service personnel.

Table 28: SDM Specific Troubleshooting

Docking Station Specific Troubleshooting

Problem	Possible Cause	Recommended action(s)
P0600 Docking Station door does not close properly	Sensor cable jammed in the door	Adjust cable and close the Docking Station door properly
	Sensor not inserted properly in the Docking Station door	Insert the sensor properly and close the door.
	Mechanical defect of the Docking Station door	Contact qualified service personnel.
P0601 Docking Station Fault is displayed	Contaminations (e.g. gel residues) disturb the gas flow	Clean Docking Station and V-Sign™ Sensor. If problem persists contact qualified service personnel.
	Docking Station defective	Contact qualified service personnel.
P0602 "Gas leak in DS" is displayed	Docking Station door is not closed properly	Place the V-Sign™ Sensor in the dedicated holder at the inside of the Docking Station door with the sensing elements facing the SDM and close the Docking Station door.
	Docking station and/or sensor contaminated with gel residues (causing a leak)	Clean Docking Station and V-Sign™ Sensor as described in the corresponding section of the Technical Manual for the SDM. If problem persists contact qualified service personnel.
P0603 Service Gas bottle cannot be installed properly	Plastic lid of the new Service Gas bottle not removed	Remove the plastic lid and install the Service Gas bottle.
	Foreign body in the slot for the Service Gas bottle	Switch off the SDM, disconnect it from the mains supply and remove the foreign body from the slot on the rear panel of the SDM.
	Thread of the Service Gas bottle is damaged	Use a new Service Gas bottle and install it as described in Instruction Manual for the SDMS.
	SDM is defective	Contact qualified service personnel.
P0604 Consumption of the Service Gas is higher than usual and "Gas leak in DS" is not displayed	High pressure part of the Docking Station Module is leaky	Contact qualified service personnel.
P0605 V-Sign™ Sensor calibration does not start, V-Sign™ Sensor LED is illuminated	Service Gas bottle empty	Use a new Service Gas bottle and install it as described in section Technical Manual for the SDM.
	V-Sign™ Sensor temperature is too low	Wait until the sensor temperature is less than 0.5 °C below the SET temperature. If problem persists contact qualified service personnel.

Table 29: Docking Station Specific Troubleshooting

Annex

Menus
Menu Structure

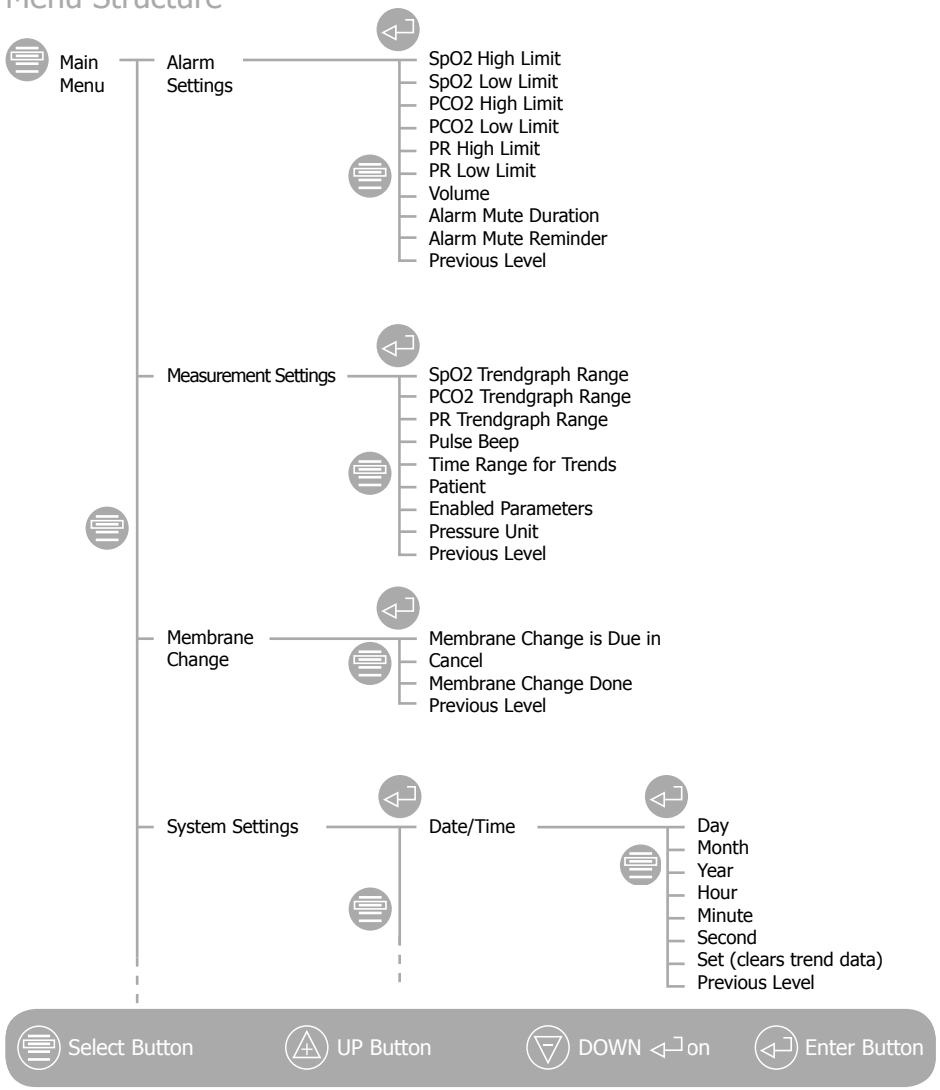


Figure 4: Menu Structure 1/2

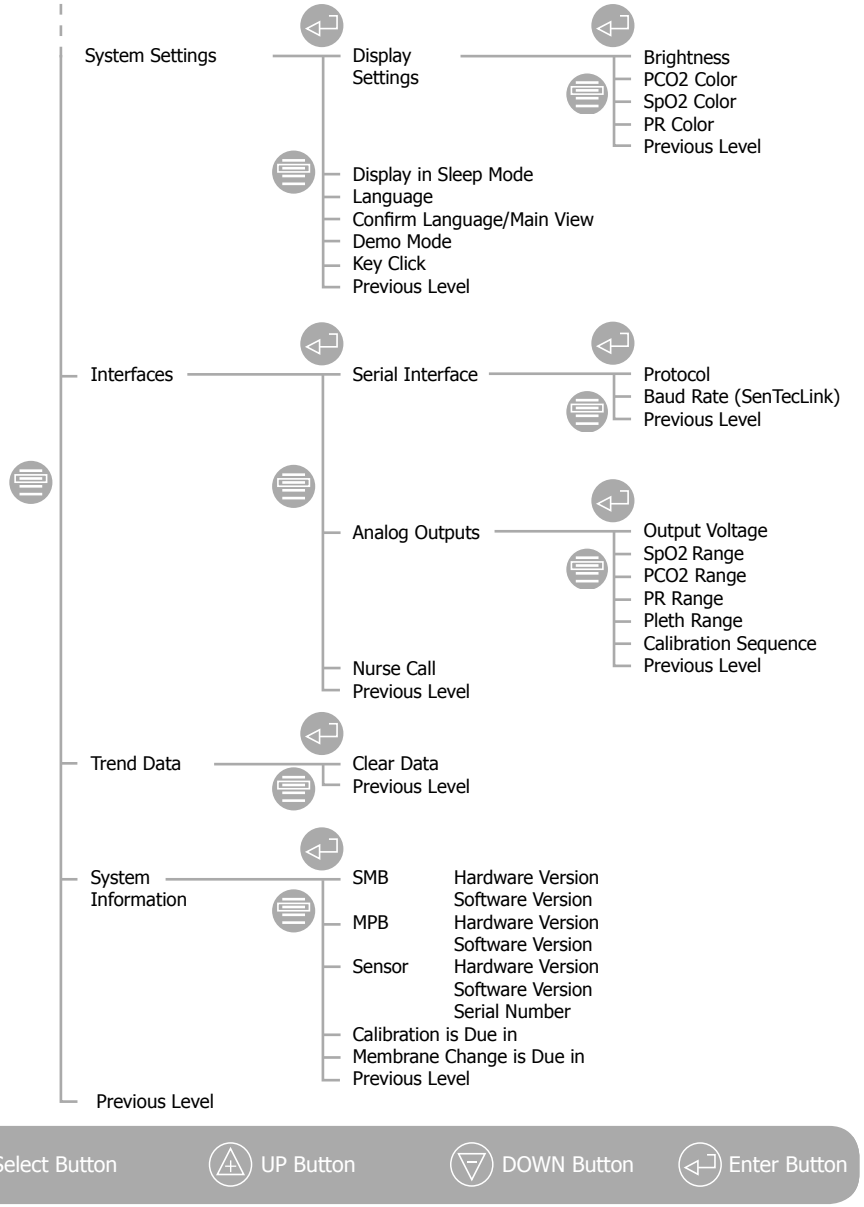


Figure 5: Menu Structure 2/2

Use the **Select button** to activate the Menu Mode and to cycle through the selectable items. Use the **UP** and **DOWN** buttons to increase or decrease a selectable, variable parameter. Use the **Display** Button to leave the Menu Mode and to return to the measurement display.

Use the **Select button** to activate the Menu Mode and to cycle through the selectable items. Use the **UP** and **DOWN** buttons to increase or decrease a selectable, variable parameter. Use the **Display** Button to leave the Menu Mode and to return to the measurement display.

The following tables list the menu items of the SDM. They identify the menu item type (sub-menu, function, or parameter), default values, parameter ranges with the corresponding unit, options available and data formats.

The default values correspond to the factory settings of a parameter. The SDM will retain user changes to the following parameters after switching OFF and ON again:

- SpO2 High Limit
- SpO2 Low Limit
- PCO2 High Limit
- PCO2 Low Limit
- PR High Limit
- PR Low Limit
- Volume
- Alarm Mute Duration
- Alarm Mute Reminder
- SpO2 Trendgraph Range
- PCO2 Trendgraph Range
- PR Trendgraph Range
- Pulse Beep
- Time Range for Trends
- Patient
- Enabled Parameters
- Pressure Unit
- Brightness
- SpO2 Color
- PCO2 Color
- PR Color
- Display in Sleep Mode
- Language
- Key Click
- Protocol (Serial Interface)
- Baud Rate (SenTecLink)
- SpO2 Range (Analog Outputs)
- PCO2 Range (Analog Outputs)
- PR Range (Analog Outputs)
- Nurse Call

Note: The SDM also retains user changes for the "Data recording interval", the "Patient ID" and the "display of PCO_2 calibration curve". These parameters can only be changed by using "V-STATS" (PC-Software for the SDM), i.e. they can NOT be changed in the menu of the SDM.

Main Menu (1st level)

Menu Item	Type
Alarm Settings	sub-menu
Measurement Settings	sub-menu
Membrane Change	sub-menu
System Setting	sub-menu
Interfaces	sub-menu
Trend Data	sub-menu
System Information	sub-menu
Previous Level	

Table 30: Main Menu

Note: The sub-menu "Membrane Change" is not accessible if the sensor is on the patient, in the Docking Station, or if the parameter PCO_2 is disabled.

Alarm Settings (2nd level)

Menu Item	Type	Default	Range [unit] / Options
SpO2 High Limit	Parameter	100%	(SpO_2 Low Limit + 5) ... 100 [%]
SpO2 Low Limit	Parameter	85%	0 ... (SpO_2 High Limit – 5) [%]
PCO2 High Limit	Parameter	45 mmHg	(PCO_2 Low Limit + 5) ... 200 [mmHg]
		6.0 kPa	(PCO_2 Low Limit + 0.6) ... 26.0 [kPa]
PCO2 Low Limit	Parameter	30 mmHg	0 ... (PCO_2 High Limit – 5) [mmHg]
		4.0 kPa	0.0 ... (PCO_2 High Limit – 0.6) [kPa]
PR High Limit	Parameter	120 bpm	(PR Low Limit + 10) ... 250 [bpm]
PR Low Limit	Parameter	50 bpm	30 ... (PR High Limit – 10) [bpm]
Volume	Parameter	3	1 (low) ... 5 (high)
Alarm Mute Duration	Parameter	1 min	1, 2 [min]
Alarm Mute Reminder	Parameter	ON	ON, OFF
Previous Level	–	–	–

Table 31: Menu "Alarm Settings"

Measurement Settings (2nd level)

Menu Item	Type	Default	Range [unit] / Options
SpO2 Trendgraph Range	Parameter	85-100%	0-100, 50-100, 70-100, 85-100 [%]
PCO2 Trendgraph Range	Parameter	25-55 mmHg	10-50, 25-55, 25-75, 35-100, 60-140, 75-200,
		3.5-7.5 kPa	120-200, 0-75, 0-100, 0-200 [mmHg]1.5-7.0,
			3.5-7.5, 3.5-10.0, 4.5-15.0, 8-18.0, 10.0-27.0,
			16.0-27.0, 0-10.0, 0-15.0, 0-27.0 [kPa]
PR Trendgraph Range	Parameter	30-125 bpm	30-80, 30-125, 50-120, 100-250, 30-250 [bpm]
Pulse Beep	Parameter	OFF	ON, OFF
Time Range for Trends	Parameter	30 min	15, 30, 60, 120 [min], 4, 8, 12, 24, 36, 48 [h]
Patient	Parameter	Adult	Adult, Neonatal
Enabled Parameters	Parameter	PCO2 SPO2 PR	"PCO2 SPO2 PR", "PCO2", "SpO2 PR"
Pressure Unit	Parameter	mmHg	mmHg, kPa
Previous Level	--	--	--

Table 32: Menu "Measurement Settings"

Note: In case of a volatile memory the maximal selectable "Time Range for Trends" is 12 hours for a data recording interval of 1 sec and 24 hours for a data recording interval of 2 sec. In case of a non-volatile Flash memory the maximal selectable "Time Range for Trends" is 36 hours for a data recording interval of 1 sec.

Note: If the sensor is on the patient the patient type can not be changed.

Note: If the menu parameter "Patient" is set to "Neonatal", the option "Enabled Parameters" is automatically set to "PCO2" and can not be changed by the user.

Note: In order to maintain display quality at a reasonable level, the maximal selectable "Time Range for Trends" is intentionally limited to 48 hours.

Membrane Change (2nd level)

Menu Item	Type	Default	Range [unit] / Options
Membrane Change is Due in	Information	--	Indicates how many days are left until the change of the sensor membrane will be requested by the SDM
Cancel	Function	--	To "Cancel" the confirmation of the membrane change / Returns to measurement display
Membrane Change Done	Function	--	To confirm the change of the sensor membrane / Returns to measurement display
Previous Level	--	--	--

Table 33: Menu "Membrane Change"

System Settings (2nd level)

Menu Item	Type	Default	Range [unit] / Options
Date/Time	Sub-menu	--	--
Display Settings	Sub-menu	--	--
Display in Sleep Mode	Parameter	OFF	ON, OFF
Language	Parameter	english	čeština, dansk, deutsch, english, español, français, italiano, ニホンゴ (japanese - Katakana), polski, nederlands, português, svenska, türkçe
Confirm Language/ Main View	Function	--	Activates the selected language / returns to measurement displsay
Demo Mode	Parameter	OFF	ON, OFF
Key Click	Parameter	ON	ON, OFF
Previous Level	--	--	--

Table 34: Menu "System Settings"

Note: If the sensor is on the patient i) the sub-menu "Date/Time" is not accessible and ii) the "Demo Mode" can not be activated.

Date/Time (3rd level)

Menu Item	Type	Format	
Day	Parameter	DD	--
Month	Parameter	MM	--
Year	Parameter	YYYY	--
Hour	Parameter	HH	--
Minute	Parameter	MM	--
Second	Parameter	SS	--
Set (clears trend data)	Function	--	To activate the new "Date/Time" setting
Previous Level	--	--	--

Table 35: Menu "Date/Time"

Note: The internal memory will be cleared when changing Date/Time of the SDM.

Note: It is possible to change Date/Time by using "V-STATS" (PC-Software for the SDM).

Display Settings (3rd level)

Menu Item	Type	Default	Range [unit] / Options
Brightness	Parameter	100	0-100
PCO2 Color	Parameter	Green	Red, Green, White, Blue, Orange, Yellow, Fuchsia, Cyan
SpO2 Color	Parameter	Red	Red, Green, White, Blue, Orange, Yellow, Fuchsia, Cyan
PR Color	Parameter	White	Red, Green, White, Blue, Orange, Yellow, Fuchsia, Cyan
Previous Level	--	--	--

Table 36: Menu "Display Settings"

Interfaces (2nd level)

Menu Item	Type	Default	Range [unit] / Options
Serial Interface	Sub-menu	--	--
Analog Outputs	Sub-menu	--	--
Nurse Call	Parameter	ON	ON, OFF
Previous Level	--	--	--

Table 37: Menu "Interfaces"

Serial Interface (3rd level)

Menu Item	Type	Default	Range [unit] / Options
Protocol	Parameter	SenTecLink	OFF, SenTecLink, Philips VueLink, Philips VueLink 2, Spacelabs Flexport, SenTec Datalogger

Baud Rate (SenTecLink)	Parameter	115’200	19’200, 38’400, 57’600, 115’200 **Note:** Only changeable for the protocol “SenTecLink”
Previous Level	--	--	--

Table 38: Menu “Serial Interface”

Analog Outputs (3rd level)

Menu Item	Type	Default	Range [unit] / Options
Output Voltage	Information	--	--
SpO2 Range	Parameter	85-100%	0-100, 50-100, 70-100, 85-100 [%]
PCO2 Range	Parameter	25-55 mmHg 3.5-7.5 kPa	10-50, 25-55, 25-75, 35-100, 60-140, 75-200, 120-200, 0-75, 0-100, 0-200 [mmHg] 1.5-7.0, 3.5-7.5, 3.5-10.0, 4.5-15.0, 8-18.0, 10.0-27.0, 16.0-27.0, 0-10.0, 0-15.0, 0-27.0 [kPa]
PR Range	Parameter	30-125 bpm	30-80, 30-125, 50-120, 100-250, 30-250 [bpm]
Pleth Range	Information	--	--
Calibration Sequence	Function	--	Activates the calibration sequence for the analog output
Previous Level	--	--	--

Table 39: Menu “Analog Outputs”

Trend Data (2nd level)

Menu Item	Type	Default	Range [unit] / Options
Clear Data	Function	--	Deletes the Trend Data stored in the internal memory of the SDM
Previous Level	--	--	--

Table 40: Menu “Trend Data”

Note: In case of a FLASH memory, deleting the entire memory takes approximately 20 seconds.

Note: The currently active data recording interval, the free and total memory capacity are displayed in the menu “Trend Data” along with the memory type (volatile / non-volatile) of your SDM. The default value of the data recording interval is 4 sec. The data recording interval can not be changed in the menu, it only can be changed by using “V-STATS” (PC-Software for the SDM). The supported options are 1, 2, 4, and 8 seconds.

Note: The data stored in the internal memory of the SDM are deleted if the data recording interval is changed.

System Information (2nd level)

Menu Item		Type	Default	Range [unit] / Options
SMB:	Hardware Version	Information	--	--
	Software Version	Information	--	--
MPB:	Hardware Version	Information	--	--
	Software Version	Information	--	--
Sensor:	Hardware Version	Information	--	--
	Software Version	Information	--	--
	Serial Number	Information	--	--
Calibration is Due in		Information	--	--
Membrane Change is Due in		Information	--	--
Previous Level		--	--	--

Table 41: Menu “System Information”

Technical Specifications

SenTec Digital Monitor

Physical Characteristics

Weight	2.5 kg (5.5 lbs)
Size (height x width x depth)	10.2 cm x 27.0 cm x 23.0 cm (4.00" x 10.63" x 9.06")

Environmental Conditions

Transport/Storage (in original factory package

The following conditions apply for all items of the SenTec Digital Monitoring System.

Temperature	0 – 50°C
Humidity	10 – 95% (non-condensing)
Barometric pressure	375 – 800 mmHg (500 – 1060 hPa)

For the products indicated below we recommend additional long term storage conditions:

Temperature	15 - 26°C	V-Sign Sensor, Ear Clip, Multi-Site Attachment Rings, V-Sign Disposable Set, Sensor Gel, Service Gas
Humidity	40 - 60 %	Multi-Site Attachment Rings (model MAR-A/P)
	50%	Multi-Site Attachment Rings (model MAR-A/P/N)

Operation

Temperature	10 – 40°C	(instrument)
Humidity	15 – 95%	non-condensing
Altitude	-390 – 3,658 m	(-1,280 – 12,000 ft)
Barometric Pressure	525 – 800 mmHg	(700 – 1060 hPa)

Site Timer

The Site Timer controls the duration of sensor application to the patient. It is counting down from the preset site time to zero during monitoring. The Site Timer will trigger a low priority alarm when the preset site time has elapsed. The Site Timer resets when the sensor is inserted into the Docking Station.
Preset site time = 8 hours

Sensor temperature surveillance – "Sensor Fault"

Monitor detects sensor over-temperature and automatically switches off sensor power. Triggered if:

1. Actual temperature > SET temperature + predefined value
2. Actual temperature > predefined value
3. Difference between the analogue and digital T measurements > predefined value
4. No temperature reading available from the sensor
5. Temperature measurement frozen

Note: Sensor temperature is supervised and controlled primarily on the sensor itself. The SDM's supervision is for redundancy.

Display

Colour display (640x240 pixels, VGA, TFT) showing:

- Trend graphs and numeric values of the measurement parameters
- Plethysmographic waveform or blip bar presentation of the pulse (if available)
- High and low alarm limits for each physiological measurement parameter
- Status messages such as "Sensor off patient", "Site time elapsed", "Calibrate sensor", "Battery low" or "Gas bottle empty"
- Status icons for "Site Timer", "Battery", "Sensor Temperature", "Barometric Pressure", "Gas"
- Selectable parameter color

Predefined user-selectable measurement displays, sensor calibration display, menu displays, POST screen, Ready for use screen and Sleep Mode.

Alarms/Visual Indicators

Audible and visual indicators for high/low PCO_2, SpO_2 and PR alarms and technical alarms. Visual indicators (LED's) for audible alarms muted permanently/temporarily, ON/OFF indicator, AC power/battery indicator.

Interfaces

Serial Interface	RS-/EIA-232; supported protocols: Philips VueLink, Philips VueLink 2, Spacelabs Flexport, SenTecLink, SenTec Datalogger
Analog output	0 – 1 V for PCO_2, SpO_2, PR, and Pleth (selectable parameter ranges)
LAN*	Ethernet 10 Mb/s
Nurse Call capability	yes

* feature currently not available

Internal Memory

Automatic storage of measured patient data according to the FIFO (First In First Out) principle. The data can be downloaded to a personal computer (PC). The memory capacity depends on the selected data recording interval and the memory type.

Data Recording Interval [seconds]	Memory Capacity [days] Volatile memory (RAM)	Non-volatile memory (FLASH)
1	**0.5**	**1.5**
2	**1.0**	**3.0**
4 (Factory Default)	**2.0**	**6.0**
8	**4.0**	**12.0**

Note: The data recording interval can only be changed by using "V-STATS" (PC-Software for the SDM), i.e. it can NOT be changed in the menu of the SDM. The currently active data recording interval, the free and total memory capacity are displayed in the menu "Trend Data" along with the memory type (volatile / non-volatile) used in your SDM.

Note: The data stored in the internal memory of the SDM are deleted if the data recording interval is changed.

Note: If the internal memory of your SDM is volatile, the history data will be lost if the SDM is switched off.

Electrical

Power supply	100 - 240V~ (50/60Hz)
Internal battery	sealed LiIon battery
Internal battery capacity	6 h (new, fully charged battery)
Power consumption	max. 450 mA
Mode of operation	suitable for continuous operation

The correct type and rating of live and neutral fuses must always be used.

Electrical Safety

Type of protection against electrical shock	Class I (if AC powered) Class I (with internal reserve power source, i.e. if battery powered)
Degree of protection against electrical shock	Type BF, APPLIED PART – DEFIBRILLATION PROOF
Degree of protection against harmful ingress of water	IPX1
Degree of safety in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Not suitable

Calibration/Docking Station

Calibration chamber	Integrated calibration chamber (Docking Station) with one-gas calibrator
Calibration duration	Typically 5 minutes (varies between 3 and 14 minutes)
Calibration mode	Fully automatic. Calibration starts upon insertion of sensor into Docking Station. If stored in the Docking Station the V-Sign™ Sensor is periodically recalibrated.
Calibration Interval	8 hours (Note: 4-hours interval after switching on the SDM/ sensor, after membrane change, after changing Date/Time by more than 5 minutes, after changing the patient type, after prolonged ambient air exposure of the sensor > 30 min, after the Docking Station surveillance has detected a gas leak)
Barometric pressure	Measured automatically by a built-in barometer
Gas leak detection	To ensure calibration reliability the SDM automatically tests the Docking Station for gas leaks. If a leak is detected a low priority alarm sounds and the message "Gas leak in DS" is displayed.

Service Gas

WARNING: Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50°C (122°F). Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material.

WARNING: Do not use gas bottles from manufacturers other than SenTec. The use of non-SenTec gas bottles may damage the Docking Station. Wrong calibration gas mixtures will result in wrong sensor calibrations and subsequently result in wrong PCO_2 data.

Volume	0,56 l
Contents	GAS-0812 5.7 l, 9.5 bar (137.786 PSI) at 21°C (70°F)
Net weight	7 g
Components	8.00 ± 0.05% CO_2 (carbon dioxide) 12.00 ± 0.05% O_2 (oxygen) balance N_2 (nitrogen)
Service Gas cylinder	TRG 300; 75/324/EWG; 94/1/EG; D.O.T.-2Q; Aerosol UN 1950 Non-flammable gas max. operating pressure: 12 bar (174 PSI) deformation pressure: >18 bar (261 PSI) burst pressure: >21.6 bar (313 PSI)

Note: Dispose of empty gas bottles according to local waste regulations for aluminum containers.

Sensor Gel

WARNING: Do not swallow. Keep out of reach of children.

WARNING: Avoid contact with eyes and injured skin.

Contents 5 ml

Biocompatibility testing has been conducted on the Sensor Gel in compliance with EN ISO 10993-1:1997, Biological Evaluation of Medical Devices, Part 1. The Sensor Gel has passed the recommended biocompatibility testing and is therefore in compliance with EN ISO 10993-1:1997. A Material Safety Data Sheet is available on request for the Sensor Gel.

V-Sign™ Sensor

Biocompatibility testing has been conducted on the V-Sign™ Sensor in compliance with EN ISO 10993-1:1997, Biological Evaluation of Medical Devices, Part 1. The V-Sign™ Sensor has passed the recommended biocompatibility testing and is therefore in compliance with EN ISO 10993-1:1997.

Digital microtechnology:
Opto-electronic components, micro pH-electrode, temperature sensors, and a mixed-signal micro-controller reside on a digital sensor print. Sensor specific data are stored in a digital memory chip.

Measurement principles:
Stow-Severinghaus type PCO_2 sensor combined with a 2-wavelength pulse oximeter
Sensor temperature:
Adult/Pediatric mode: SET Temperature = 42°C.
Neonatal mode: SET Temperature = 41°C

Reliable and safe control by two independent circuits. Accuracy: +/- 0.2°C

Sensor temperature surveillance - "Temp. limiter active":
Sensor detects sensor over-temperature and automatically switches off its power consuming parts. Triggered if:

1. Current temperature > SET temperature + 0.2 °C
2. Current temperature > 44.6°C

Note: Second level redundant temperature control is implemented in the Sentec Digital Monitor

Heating power: 0 - 1000 mW, typically < 500 mW

Interference with anesthetic gases:
Negligible (based on literature about Stow-Severinghaus type PCO_2 sensors)

Sensor LED characteristic: wavelength: 660 nm + 880 nm
energy: < 15 mW

Sensor membrane change:
Under normal use conditions, change of the sensor membrane is required every 28 days.

Physical specifications:

Size (diameter x height)	14 mm x 9 mm
Weight (sensor head)	< 3 g
Waterproof	
Cable	highly flexible, shielded, polyurethane coated

For additional information on the V-Sign™ Sensor refer to the sensor's Directions for Use.

Ear Clip

Biocompatibility testing has been conducted on the SenTec Ear Clip in compliance with EN ISO 10993-1:1997, Biological Evaluation of Medical Devices, Part 1. The SenTec Ear Clip has passed the recommended biocompatibility testing and is therefore in compliance with EN ISO 10993-1:1997.

For detailed information on the SenTec Ear Clip refer to the sensor fixation's Directions for Use.

Multi-Site Attachment Ring

Biocompatibility testing has been conducted on the Multi-Site Attachment Ring, models MAR-A/P and MAR-A/P/N, in compliance with EN ISO 10993-1:1997, Biological Evaluation of Medical Devices, Part 1. The Multi-Site Attachment Ring has passed the recommended biocompatibility testing and is therefore in compliance with EN ISO 10993-1:1997.

For detailed information on the Multi-Site Attachment Ring refer to the respective Directions for Use.

System Performance: SDM with V-Sign™ Sensor

Carbon Dioxide Partial Pressure (PCO_2)

Measurement range	0 – 200 mmHg	(0 – 26.7 kPa)
Resolution	0.1 mmHg	(0.1 kPa)
Drift (in vitro)	typically < 1%/h	
Response time (T90)	typically < 80 s	

An algorithm proposed by JW. Severinghaus is used to estimate arterial PCO_2 from the measured cutaneous $PcCO_2$. This algorithm accounts for temperature and metabolic correction factors, i.e. the SDM displays a 37°C PCO_2 value.

Oxygen Saturation (SpO_2)

Measurement range	1 – 100%
Resolution	1%
Accuracy	70 – 100%: ± 2% (1 standard deviation, A_{rms})

Note: The SDMS measures functional oxygen saturation.

SpO_2 accuracy specification is based on controlled hypoxia studies on healthy, adult volunteers over the specified saturation range with the V-Sign™ Sensor applied to the earlobe. Pulse oximeter SpO_2 readings were compared to SaO_2 values of blood samples measured by hemoximetry. SpO_2 accuracy is expressed as A_{rms} (root-mean-square). The indicated variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population.

Pulse Rate (PR)

Measurement range	30 – 250 bpm (beats per minute)
Resolution	1 bpm
Accuracy	± 3 bpm

sensTec

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